Acetaminophen

Drug Description

Acetaminophen (APAP, paracetamol) is a para-aminophenol analgesic and the active metabolite of phenacetin. Due to the toxic effects of phenacetin at therapeutic doses and the availability of acetaminophen, phenacetin is no longer used. Acetaminophen possesses analgesic and antipyretic activity similar to aspirin; however, acetaminophen has no peripheral antiinflammatory activity or effects on platelet function. Acetaminophen was first used in clinical medicine in the 1890's. It is effective in the relief of both acute and chronic pain and may be preferred over NSAIDs due to fewer hematologic, GI, and renal effects. Acetaminophen is the preferred analgesic/antipyretic for patients in whom aspirin is contraindicated and in those with underlying renal disease for episodic, though not chronic, use.[23977] In addition, acetaminophen has been recommended by the American Lung Association as the first line treatment for aches and pains associated with the flu, by the American Geriatrics Society for both minor and persistent pain in elderly patients [35614], and by the American College of Rheumatology as first-line therapy for osteoarthritis of the hip or knee [35976]. The drug has a history of safe and effective use; however, unintentional or intentional misuse of acetaminophen is the number one cause of acute hepatic failure in the U.S.[32202] Acetaminophen was first approved by the FDA in 1950. Intravenous acetaminophen (Ofirmev) was approved by the FDA in November 2010 for the treatment of pain and fever in adults, adolescents, and children over the age of 2 years.[42289]

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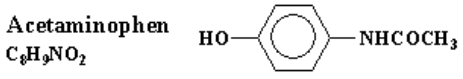
Classifications

Analgesics

Analgesic/Acetaminophen

Chemical Structures



Mechanism of Action

Mechanism of Action: The exact mechanism of action is unknown, but acetaminophen is thought to mediate its actions centrally through activation of the descending serotonergic pathways. Acetaminophen is believed to increase the pain threshold by inhibiting prostaglandin (PG) synthesis through the cyclooxygenase (COX) pathway, similar to nonsteroidal anti-inflammatory drugs (NSAIDs). Though acetaminophen's analgesic and antipyretic properties are similar to those of NSAIDs, acetaminophen does not have significant anti-inflammatory or antiplatelet effects. It has been suggested acetaminophen may inhibit a specific site on the prostaglandin H_2 synthetase (PGHS) molecule, the 2 isoforms of which, PGHS1 and PGHS2, are commonly referred to as COX-1 and COX-2. PGHS has 2 active sites, COX and peroxidase (POX). Acetaminophen acts as a reducing cosubstrate at the POX site and interferes with the conversion of arachidonic acid to PGH_2, thereby inhibiting PG synthesis. Other potential mechanisms may involve inhibition of the nitric oxide pathway mediated by a variety of neurotransmitter receptors (e.g., N-methyl-D-aspartate and substance p) and indirect activation of cannabinoid receptors. Acetaminophen produces its antipyretic effect by inhibiting PG synthesis in the CNS and blocking the actions of endogenous pyrogens at the hypothalamic thermoregulatory centers.[54019] [54020]

When supratherapeutic or repeated therapeutic doses of acetaminophen are consumed, hepatic stores of glucuronide and sulfate are depleted, resulting in an increased formation of N-acetyl-para-benzoquinoneimine (NAPQI), which is normally bound to and detoxified by glutathione. Insufficient glutathione results in NAPQI binding to cytosol proteins in the tissue, leading to cellular necrosis of the liver. Like the liver, the kidney is also susceptible to acetaminophen toxicity and may form a toxic metabolite when it is glutathione depleted. Administration of N-acetylcysteine may reduce toxicity by regenerating glutathione. Hepatic necrosis and failure after acute overdose may be less common in young children than in older children and adults. This may be related to reduced rates of metabolism by the CYP450 system and/or an increased ability to synthesize glutathione.[54022] [54023] [54024]

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Pharmacokinetics

Pharmacokinetics: Acetaminophen is administered orally, rectally, or intravenously. At therapeutic concentrations, protein binding is about 10—25%. Acetaminophen is widely distributed throughout most body tissues except fat; low protein binding and molecular weight allow blood-brain barrier penetration. Vd is approximately 1 L/kg.

Acetaminophen is primarily metabolized in the liver by first-order kinetics and involves 3 separate pathways: glucuronidation, sulfate conjugation,

and cytochrome P450 (CYP450) oxidation. Glucuronidation and sulfate conjugation are the major routes of metabolism, while a small amount of drug undergoes oxidative metabolism via CYP2E1 producing the hepatotoxic metabolite, N-acetyl-p-benzoquinonimine (NAPQI). At therapeutic doses, NAPQI is rapidly conjugated with glutathione to form inert cysteine and mercapturic acid metabolites. The P450 isoenzymes 1A2 and 3A4 appear to have a minor role in the metabolism of acetaminophen. Supratherapeutic or repeated therapeutic doses of acetaminophen, fasting, and alcoholism may deplete glutathione stores, leading to increased concentrations of NAPQI and hepatotoxicity. The elimination half-life of acetaminophen is 2—3 hours in healthy adult patients. Acetaminophen is renally excreted primarily as the glucuronide conjugate (40—65%) and sulfate metabolite (25—35%). Mercapturic acid and cysteine metabolites account for 5—12% of the urinary metabolites; less than 5% is excreted as unchanged drug.[25460] [28100] [42289] [54020]

Affected cytochrome P450 isoenzymes: CYP2E1
Although acetaminophen is primarily metabolized via glucuronidation and sulfate conjugation, it is also a substrate of CYP2E1. Drugs that induce CYP2E1 may increase the metabolism of acetaminophen to its toxic metabolite and therefore increase the risk of hepatotoxicity. Because CYP1A2 and CYP3A4 have negligible contribution to acetaminophen metabolism, the enzymes are unlikely to affect toxic metabolite formation.[25460] [42289] [54020]

•Route-Specific Pharmacokinetics
Oral Route
Immediate-release acetaminophen is rapidly and almost completely absorbed from the gastrointestinal (GI) tract, primarily the small intestine. Bioavailability ranges from 85—98%. Peak plasma concentrations occur within 30—60 minutes and range from 7.7—17.6 mcg/ml after a single 1000 mg dose and 7.9—27 mcg/mL at steady state after 1000 mg every 6 hours in adult patients.[54020] In a study of febrile children 2—7 years of age, acetaminophen 12 mg/kg achieved maximum concentration (14.6 +/- 2.6 mcg/ml) within 0.55 +/- 0.08 hours.[54026] Maximum concentrations of acetaminophen are delayed with concurrent food administration, however the extent of absorption is not affected.[54020]

Intravenous Route
The maximum concentration after administration of an IV dose of acetaminophen is up to 70% higher than that seen after the same dose is given orally; however, the overall exposure, described by area under the concentration time curve (AUC), is similar. The pharmacokinetic profile of IV acetaminophen in adults is dose proportional after administration of single doses of 500, 650, and 1000 mg.[42289]

Other Route(s)
Rectal Route
Rectal absorption of acetaminophen is prolonged and highly variable compared to other routes of administration; reported bioavailability ranges from 6.5—98%. Several factors may influence absorption, including lipophilicity of the vehicle, placement of the suppository, rectal contents, premature defecation of the suppository, suppository size, number of suppositories administered, and/or rectal pH. Compared to adult patients, pediatric patients appear to absorb acetaminophen from suppositories to a greater extent.[54111] [54112] [54115] [54116]

•Special Populations
Hepatic Impairment
The half-life of acetaminophen may be prolonged in patients with hepatic disease.[54020] [54066]

Renal Impairment
In severe renal impairment (CrCl 10—30 mL/min), the elimination of acetaminophen is slightly delayed, with an elimination half-life of 2—5.3 hours. In addition, the elimination of sulfate and glucuronide conjugates is 3 times slower in patients with severe renal impairment than in healthy subjects, leading to potential accumulation.[54126] [54127] [54131]

Pediatrics
Neonates and Infants
Slow and erratic gastric emptying in the neonate leads to a slower rate of oral acetaminophen absorption (0.21 hours); adult rates are reached by 6 to 8 months of age. Rectal absorption of an acetaminophen suppository decreases with increasing age; perhaps attributable to rectal insertion height and consequent rectal venous drainage patterns. Because of fetal body composition and water distribution, premature neonates and young infants have a slightly larger Vd compared to older pediatric patients and adults. At 28 weeks postconceptual age (PCA), Vd is 1.47 L/kg, whereas at 60 weeks PCA Vd is 1.04 L/kg.[54144] The AUC of acetaminophen in neonates and infants is higher (62 and 57 mcg x hour/mL, respectively) than that of children and adolescents (38 and 41 mcg x hour/mL, respectively) after a single IV dose of 15 mg/kg. Dosing simulations suggest that a dose reduction of 50% in neonates up to 28 days old and a reduction of 33% in infants 1 month to less than 2 years should produce a similar AUC to that seen in children 2 years of age and older.[42289] Neonates and infants have a lower risk of acetaminophen-induced hepatotoxicity compared to older children and adults because of hepatic enzyme immaturity (specifically CYP2E1, which is responsible for producing the hepatotoxic metabolite NAPQI).[56547] However, immature hepatic pathways also result in a delayed drug clearance. In neonates, sulfate conjugation is pronounced, while glucuronide conjugation is deficient. The relative contribution of sulfate and glucuronide conjugation changes with age and normal adult ratios (2:1 glucuronide to sulfate conjugates) are reached by late childhood. Acetaminophen clearance also has great interpatient variability and appears to increase with patient weight and age. Clearance increases from 28 weeks PCA (0.01 L/kg/hour) with a maturation half-life of 11.3 weeks to reach 0.15 L/kg/hour by early infancy (60 weeks PCA); clearance approaches adult values by 1 year of age. Additionally, clearance may be reduced in the presence of high unconjugated bilirubin concentrations.[54114] [54117] [54118] Approximate half-

life of acetaminophen is as follows: neonate gestational age 28 to 32 weeks = 11 hours, neonate gestational age 32 to 36 weeks = 5 hours, term neonate = 3 to 7 hours, infant = 4 hours.[42289] [54119] [54120] [54121]

Children and Adolescents
Acetaminophen is excreted primarily as the sulfate conjugate in children, due to a deficiency in glucuronide formation in younger pediatric patients. The relative contribution of sulfate and glucuronide conjugation changes with age and normal adult ratios (2:1 glucuronide to sulfate conjugates) are reached by 12 years of age.[25459] [54114] The AUC of acetaminophen in children and adolescents after a single IV dose of 15 mg/kg (38 and 41 mcg x hour/mL, respectively) is similar to that in adults after a single IV dose of 1000 mg (43 mcg x hour/mL). In addition, the mean half-life of IV acetaminophen in pediatric patients is longer than the half-life in adults, with younger patients having the slowest clearance (neonates = 7 hours, infants = 4.2 hours, children = 3 hours, adolescents = 2.9 hours, adults = 2.4 hours). Dosing simulations suggest that a dose reduction of 33% in children younger than 2 years should produce a similar AUC to that seen in children 2 years of age and older.[42289]

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Indications

Labeled

- arthralgia
- dental pain
- dysmenorrhea
- fever
- headache
- mild pain
- moderate pain
- musculoskeletal pain
- myalgia
- osteoarthritis
- severe pain

Off-Label, Recommended

- migraine †

† Off-label indication

NOTE: The FDA has advised healthcare professionals to discontinue prescribing and dispensing of combination prescription medications containing > 325 mg acetaminophen per dosage unit. This action has been taken to reduce the risk of liver damage and severe hypersensitivity reactions associated with acetaminophen.[43086] [56615] Maximum daily doses of acetaminophen are based on all routes of administration (e.g., intravenous, oral, rectal) and all products containing acetaminophen, including combination products. Exceeding maximum daily doses may result in hepatic injury, hepatic failure, and death.[42289]

For the treatment of mild pain or fever; or for the temporary relief of headache, myalgia, back pain, musculoskeletal pain, dental pain (e.g., toothache), dysmenorrhea, arthralgia, or minor aches and pains associated with the common cold or flu:
NOTE: Acetaminophen should not be used for self-medication of pain for longer than 10 days in adults or 5 days in children. In addition, acetaminophen should not be used for self-medication of marked fever (greater than 39.5 degrees C or 103.1 degrees F), fever persisting longer than 3 days, or recurrent fever, unless directed by a physician.
Oral dosage (immediate-release formulations):
Adults: 325 to 650 mg PO every 4 to 6 hours, as needed. Alternatively, 1,000 mg PO, 2 to 4 times per day can be given. It is important to note that doses effective for acute pain relief (1 to 2 tablets/day) may not be effective in chronic pain states, which require higher daily doses. Do not exceed 1 g/dose or 4 g/day.
Children and Adolescents weighing 60 kg or more: 325 mg to 650 mg PO every 4 to 6 hours as needed. Alternatively, 1,000 mg PO every 6 hours as needed. Max single dose: 1,000 mg/dose. Max daily dose: 4,000 mg/day.[52221] [54020] [54150]
Children and Adolescents weighing less than 60 kg: 10 to 15 mg/kg/dose PO every 4 to 6 hours as needed. Max single dose: 15 mg/kg/dose or 1,000 mg/dose, whichever is less. Max daily dose: 75 mg/kg/day or 4,000 mg/day, whichever is less.[54020] [54154]
Infants: 10 to 15 mg/kg/dose PO every 4 to 6 hours as needed. Max single dose: 15 mg/kg/dose. Max daily dose: 75 mg/kg/day.[54020] [54154]
Term Neonates 10 days and older: 10 to 15 mg/kg/dose PO every 4 to 8 hours as needed. Some experts recommend an initial load of 20 mg/kg PO. Max: 90 mg/kg/day. Do not exceed 48 consecutive hours at the maximum dose.[52218] [54157]
Term Neonates younger than 10 days old: 10 to 15 mg/kg/dose PO every 6 to 8 hours as needed. Some experts recommend an initial load of 20 mg/kg PO. Max: 60 mg/kg/day. Do not exceed 48 consecutive hours at the maximum dose.[52218] [54157]
Premature Neonates 32 to 36 weeks postmenstrual age: 10 to 15 mg/kg/dose PO every 8 hours as needed. Some experts recommend an initial load of 20 mg/kg PO. Max: 60 mg/kg/day. Do not exceed 48 consecutive hours at the maximum dose.[52218] [54157]
Premature Neonates 28 to 31 weeks postmenstrual age: 10 to 15 mg/kg/dose PO every 12 hours as needed. Some experts recommend an initial load of 20 mg/kg PO. Max: 40 mg/kg/day. Do not exceed 48 consecutive hours at the maximum dose.[52218] [54157]
Oral dosage (extended-release formulations):
Adults, Adolescents, and Children 12 years and older: 650 mg to 1,300 mg PO every 8 hours as needed. Max single dose: 1,300 mg/dose. Max daily

dose: 3,900 mg/day.[54020]
Children younger than 12 years: Safety and efficacy have not been established.
Rectal dosage:
Adults, Adolescents, and Children weighing 60 kg or more: 325 to 650 mg PR every 4 to 6 hours as needed. Alternatively, 1,000 mg PR, 2 to 4 times per day can be given. It is important to note that doses effective for acute pain relief may not be effective in chronic pain states, which require higher daily doses. Do not exceed 1 g/dose or 4 g/day.[52221]
Children and Adolescents weighing less than 60 kg: 10 to 20 mg/kg/dose PR every 4 to 6 hours as needed. Max single dose: 20 mg/kg/dose or 1,000 mg/dose, whichever is less. Max daily dose: 100 mg/kg/day or 4,000 mg/day, whichever is less. High-dose rectal acetaminophen (25 to 45 mg/kg/dose) has been studied and recommended as an initial loading dose for pain management, as well as for the scheduled management of peri- and postoperative pain in pediatric patients. Its use is controversial, as optimal dosing has not been established.[54111] [54116] [54150] [54153] [54154]
Infants: 10 to 20 mg/kg/dose PR every 4 to 6 hours as needed. Max single dose: 20 mg/kg/dose. Max daily dose: 75 mg/kg/day. High-dose rectal acetaminophen (25 to 45 mg/kg/dose) has been studied and recommended as an initial loading dose for pain management, as well as for the scheduled management of peri- and postoperative pain in pediatric patients. Its use is controversial, as optimal dosing has not been established.[32702] [54111] [54153] [54154]
Term Neonates 10 days and older: 20 mg/kg/dose PR every 6 to 8 hours as needed. Some experts recommend an initial load of 30 mg/kg PR. Max: 90 mg/kg/day. Do not exceed 48 consecutive hours at the maximum dose.[52218] [54121] [54157]
Term Neonates 0 to 9 days: 20 mg/kg/dose PR every 6 to 8 hours as needed. Some experts recommend an initial load of 30 mg/kg PR. Max: 60 mg/kg/day. Do not exceed 48 consecutive hours at the maximum dose.[52218] [54121] [54157]
Premature Neonates 32 to 36 weeks postmenstrual age: 20 mg/kg/dose PR every 8 hours as needed. Some experts recommend an initial load of 30 mg/kg PR. Max: 60 mg/kg/day. Do not exceed 48 consecutive hours at the maximum dose.[52218] [54157]
Premature Neonates 28 to 31 weeks postmenstrual age: 15 mg/kg/dose PR every 12 hours as needed. Some experts recommend an initial load of 20 mg/kg PR. Max: 40 mg/kg/day. Do not exceed 48 consecutive hours at the maximum dose.[52218] [54157]
Intravenous dosage:
Adults and Adolescents weighing 50 kg or more: 1,000 mg IV every 6 hours or 650 mg IV every 4 hours as needed. Max single dose: 1,000 mg/dose. Max daily dose: 4,000 mg/day.[42289]
Adults, Adolescents, and Children 2 years and older weighing less than 50 kg: 15 mg/kg/dose IV every 6 hours or 12.5 mg/kg/dose IV every 4 hours as needed. Max single dose: 15 mg/kg/dose or 750 mg/dose, whichever is less. Max daily dose: 75 mg/kg/day or 3,750 mg/day, whichever is less.[42289]
Infants† and Children younger than 2 years†: 7.5 to 15 mg/kg/dose IV every 6 hours as needed is the dose most commonly used in infants according to a survey of anesthetists in the United Kingdom. Max single dose: 15 mg/kg/dose. Max daily dose: 60 mg/kg/day.[54132] According to FDA-approved labeling, 10 mg/kg/dose IV every 6 hours (a dose reduction of 33%) will produce a similar AUC in infants and children younger than 2 years as compared to older children.[42289]
Term Neonates†: Limited data available; dose not established. A loading dose of 20 mg/kg IV, then 7.5 to 15 mg/kg/dose IV every 6 hours as needed has been suggested. Max single dose: 15 mg/kg/dose. Max daily dose: 60 mg/kg/day.[54118] [54141] [54142] [56547] According to FDA-approved labeling, 7.5 mg/kg/dose IV every 6 hours (a dose reduction of 50%) will produce a similar AUC in neonates as compared to children older than 2 years of age.[42289] For scheduled postoperative analgesia in neonates, decreasing the dose by 50% after 4 days of continuously scheduled acetaminophen has been recommended; do not exceed 6 days of scheduled acetaminophen therapy.[42289] [54118] [54141] [54142]
Premature Neonates† 32 to 36 weeks postmenstrual age: Limited data available; dose not established. A loading dose of 20 mg/kg IV, then 10 mg/kg/dose IV every 8 hours as needed has been recommended.[54141] [54118] Alternatively, 7.5 to 10 mg/kg/dose IV every 6 hours as needed has been suggested.[42289] [54118] [54142] Max single dose: 10 mg/kg/dose. Max daily dose: 40 mg/kg/day. For scheduled postoperative analgesia in neonates, decreasing the dose by 50% after 4 days of continuously scheduled acetaminophen has been recommended; do not exceed 6 days of scheduled acetaminophen therapy.[42289] [54118] [54141] [54142]
Premature Neonates† 28 to 31 weeks postmenstrual age: Limited data available; dose not established. Some experts do not recommend use of IV acetaminophen in premature neonates less than 32 weeks PMA until sufficient pharmacokinetic and pharmacodynamic studies have been conducted.[54139] A loading dose of 20 mg/kg IV, then 10 mg/kg/dose IV every 12 hours as needed has been recommended.[54118] [54141] Alternatively, 7.5 mg/kg/dose IV every 8 hours as needed has been suggested.[42289] [54142] Max single dose: 10 mg/kg/dose. Max daily dose: 22.5 mg/kg/day. For scheduled postoperative analgesia in neonates, decreasing the dose by 50% after 4 days of continuously scheduled acetaminophen has been recommended; do not exceed 6 days of scheduled acetaminophen therapy.[42289] [54118] [54141] [54142]

For the treatment of moderate pain to severe pain with adjunctive opioid analgesics:
Intravenous dosage:
Adults and Adolescents weighing 50 kg or more: 1,000 mg IV every 6 hours or 650 mg IV every 4 hours as needed. Max single dose: 1,000 mg/dose. Max daily dose: 4,000 mg/day.[42289]
Adults, Adolescents, and Children 2 years and older and weighing less than 50 kg: 15 mg/kg/dose IV every 6 hours or 12.5 mg/kg/dose IV every 4 hours as needed. Max single dose: 15 mg/kg/dose or 750 mg/dose, whichever is less. Max daily dose: 75 mg/kg/day or 3,750 mg/day, whichever is less.[42289]
Infants† and Children younger than 2 years†: 7.5 to 15 mg/kg/dose IV every 6 hours as needed is the dose most commonly used in infants according to a survey of anesthetists in the United Kingdom. Max single dose: 15 mg/kg/dose. Max daily dose: 60 mg/kg/day.[54132] According to FDA-approved labeling, 10 mg/kg/dose IV every 6 hours (a dose reduction of 33%) will produce a similar AUC in infants and children younger than 2 years as compared to older children.[42289]
Term Neonates†: Limited data available; dose not established. A loading dose of 20 mg/kg IV, then 7.5 to 15 mg/kg/dose IV every 6 hours as needed has been suggested. Max single dose: 15 mg/kg/dose. Max daily dose: 60 mg/kg/day.[54118] [54141] [54142] [56547] According to FDA-

approved labeling, 7.5 mg/kg/dose IV every 6 hours (a dose reduction of 50%) will produce a similar AUC in neonates as compared to children older than 2 years of age.[42289] For scheduled postoperative analgesia in neonates, decreasing the dose by 50% after 4 days of continuously scheduled acetaminophen has been recommended; do not exceed 6 days of scheduled acetaminophen therapy.[42289] [54118] [54141] [54142]
Premature Neonates† 32 to 36 weeks postmenstrual age: Limited data available; dose not established. A loading dose of 20 mg/kg IV, then 10 mg/kg/dose IV every 8 hours as needed has been recommended.[54141] [54118] Alternatively, 7.5 to 10 mg/kg/dose IV every 6 hours as needed has been suggested.[42289] [54118] [54142] Max single dose: 10 mg/kg/dose. Max daily dose: 40 mg/kg/day. For scheduled postoperative analgesia in neonates, decreasing the dose by 50% after 4 days of continuously scheduled acetaminophen has been recommended; do not exceed 6 days of scheduled acetaminophen therapy.[42289] [54118] [54141] [54142]
Premature Neonates† 28 to 31 weeks postmenstrual age: Limited data available; dose not established. Some experts do not recommend use of IV acetaminophen in premature neonates less than 32 weeks PMA until sufficient pharmacokinetic and pharmacodynamic studies have been conducted.[54139] A loading dose of 20 mg/kg IV, then 10 mg/kg/dose IV every 12 hours as needed has been recommended.[54118] [54141] Alternatively, 7.5 mg/kg/dose IV every 8 hours as needed has been suggested.[42289] [54142] Max single dose: 10 mg/kg/dose. Max daily dose: 22.5 mg/kg/day. For scheduled postoperative analgesia in neonates, decreasing the dose by 50% after 4 days of continuously scheduled acetaminophen has been recommended; do not exceed 6 days of scheduled acetaminophen therapy.[42289] [54118] [54141] [54142]

For minor osteoarthritis pain:
Oral dosage:
Adults: The American College of Rheumatology has recommended acetaminophen as first-line therapy for osteoarthritis of the hip or knee. In a randomized, double-blind trial, acetaminophen 4 g/day PO was as effective as ibuprofen in doses of 2.4 or 1.2 g/day for the short-term relief of joint pain and improvement of function in patients with osteoarthritis of the knee.[25458] Due to a ceiling effect where side effects increase to negate any analgesic benefit, do not exceed single doses of 1 g/dose or 4 g/day.

For the treatment of headache pain due to acute migraine†:
Oral dosage:
Adults: Single doses of 500 to 1,000 mg PO have been utilized. Due to a ceiling effect where side effects increase to negate any analgesic benefit, do not exceed single doses of 1 g/dose or 4 g/day.
Children and Adolescents 4 years and older: 15 mg/kg PO as a single dose at the onset of attack has been evaluated in a crossover study of pediatric patients (n = 88 intent to treat analysis; n = 66 efficacy analysis; age range: 4 to 16 years) in which 3 attacks were treated separately with acetaminophen (15 mg/kg), ibuprofen (10 mg/kg), or placebo. One hour after administration, acetaminophen was more than 3 times as effective as placebo with regard to pain relief (OR 3.9, 95% CI 1.4 to 11) and complete pain resolution (OR 3.3, 95% CI 1 to 11.1); there was no difference between the active drugs. Two hours after administration, acetaminophen was not superior to placebo and inferior to ibuprofen (OR 2.2, 95% CI 1.1 to 4 for acetaminophen vs. ibuprofen). In the intent to analysis, acetaminophen was twice as effective as placebo at both 1 and 2 hours with no clear difference in efficacy between the active drugs (OR 0.9, 95% CI 0.6 to 1.3 for acetaminophen vs. ibuprofen). At 2 hours, acetaminophen provided headache alleviation in 54% of patients (compared to 37% for placebo and 68% for ibuprofen). Complete resolution occurred in 39% of acetaminophen-treated, 60% of ibuprofen-treated, and 28% of placebo-treated patients.[56544] Based on this evidence, the American Academy of Neurology and Child Neurology Society states that acetaminophen is probably effective and should be considered in the acute treatment of migraine in children.[33312]

Maximum Dosage Limits
•Adults
1,000 mg/dose PO/PR/IV or 4,000 mg/day PO/PR/IV for most formulations; some OTC formulations have lower max doses, see individual products. For the extended-release oral product, 1,300 mg/dose PO, with the same overall daily dose limits as other formulations. The total daily maximum dose of 4,000 mg is the maximum dose of acetaminophen from all sources.
•Geriatric
1,000 mg/dose PO/PR/IV or 4,000 mg/day PO/PR/IV for most formulations; some OTC formulations have lower max doses, see individual products. For the extended-release oral product, 1,300 mg/dose PO, with the same overall daily dose limits as other formulations. The total daily maximum dose of 4,000 mg is the maximum dose of acetaminophen from all sources.
•Adolescents
Weighing 60 kg or more: 1,000 mg/dose PO/IV/PR (Max daily dose: 4,000 mg/day PO/IV/PR).
Weighing 50 to 59 kg: 15 mg/kg/dose PO (Max daily dose: 75 mg/kg/day [Max: 4,000 mg/day] PO); 20 mg/kg/dose PR (Max single dose: 1,000 mg/dose PR; Max daily dose: 100 mg/kg/day [Max: 4,000 mg/day] PR); 1,000 mg/dose IV (Max daily dose: 4,000 mg/day IV).
Weighing less than 50 kg: 15 mg/kg/dose PO/IV (Max daily dose: 75 mg/kg/day [Max: 3,750 mg/day] PO/IV); 20 mg/kg/dose PR (Max daily dose: 100 mg/kg/day [Max: 4,000 mg/day] PR).
•Children
2 years and older weighing 60 kg or more: 1,000 mg/dose PO/PR (Max daily dose: 4,000 mg/day PO/PR); 15 mg/kg/dose IV (Max single dose: 750 mg/dose IV; Max daily dose: 75 mg/kg/day [Max: 3,750 mg/day] IV).
2 years and older weighing 50 to 59 kg: 15 mg/kg/dose PO (Max daily dose: 75 mg/kg/day [Max: 4,000 mg/day] PO); 20 mg/kg/dose PR (Max single dose: 1,000 mg/dose PR; Max daily dose: 100 mg/kg/day [Max: 4,000 mg/day] PR); 15 mg/kg/dose IV (Max single dose: 750 mg/dose IV; Max daily dose: 75 mg/kg/day [Max: 3,750 mg/day] IV).
2 years and older weighing less than 50 kg: 15 mg/kg/dose PO/IV (Max daily dose: 75 mg/kg/day [Max: 3,750 mg/day] PO/IV); 20 mg/kg/dose PR (Max daily dose: 100 mg/kg/day [Max: 4,000 mg/day] PR).
Younger than 2 years: 15 mg/kg/dose PO (Max daily dose: 75 mg/kg/day PO); 20 mg/kg/dose PR (Max daily dose: 100 mg/kg/day PR). Safety and efficacy of the IV formulation not established; however, doses up to 15 mg/kg/dose IV (Max daily dose: 60 mg/kg/day IV) have been used.

•Infants
15 mg/kg/dose PO (Max daily dose: 75 mg/kg/day PO); 20 mg/kg/dose PR (Max daily dose: 75 mg/kg/day PR). Safety and efficacy of the IV formulation not established; however, doses up to 15 mg/kg/dose IV (Max daily dose: 60 mg/kg/day IV) have been used off-label.
•Neonates
Term Neonates 10 days and older: 20 mg/kg PO load and 15 mg/kg/dose PO maintenance dose (Max daily dose: 90 mg/kg/day PO); 30 mg/kg PR load and 20 mg/kg/dose PR maintenance dose (Max daily dose: 90 mg/kg/day PR). Safety and efficacy of the IV formulation not established; however, loading doses up to 20 mg/kg IV and maintenance doses up to 15 mg/kg/dose IV (Max daily dose: 60 mg/kg/day IV) have been used off-label.
Term Neonates younger than 10 days: 20 mg/kg PO load and 15 mg/kg/dose PO maintenance dose (Max daily dose: 60 mg/kg/day PO); 30 mg/kg PR load and 20 mg/kg/dose PR maintenance dose (Max daily dose: 60 mg/kg/day PR). Safety and efficacy of the IV formulation not established; however, loading doses up to 20 mg/kg IV and maintenance doses up to 15 mg/kg/dose IV (Max daily dose: 60 mg/kg/day IV) have been used off-label.
Premature Neonates 32 to 36 weeks PMA: 20 mg/kg PO load and 15 mg/kg/dose PO maintenance dose (Max daily dose: 60 mg/kg/day PO); 30 mg/kg PR load and 20 mg/kg/dose PR maintenance dose (Max daily dose: 60 mg/kg/day PR). Safety and efficacy of the IV formulation not established; however, loading doses up to 20 mg/kg IV and maintenance doses up to 10 mg/kg/dose IV (Max daily dose: 40 mg/kg/day IV) have been used off-label.
Premature Neonates 28 to 31 weeks PMA: 20 mg/kg PO/PR load and 15 mg/kg/dose PO/PR maintenance dose (Max daily dose: 40 mg/kg/day PO/PR). Safety and efficacy of the IV formulation not established; however, loading doses up to 20 mg/kg IV and maintenance doses up to 10 mg/kg/dose IV (Max daily dose: 22.5 mg/kg/day IV) have been used off-label.

Patients with Hepatic Impairment Dosing
Use with caution in patients with hepatic dysfunction. In patients with chronic hepatic disease, acetaminophen can be used safely; use the smallest dose for the shortest duration necessary.[23562] [54020] [54066]

Patients with Renal Impairment Dosing
CrCl<= 30 mL/min: Reduced dosing and prolonged intervals are recommended for IV dosing; however no quantitative recommendations are available. For a CrCl < 10 mL/min, administer acetaminophen (all dosage forms) at a minimum interval of every 8 hours. Chronic use should be discouraged in patients with underlying renal disease.[32569] [42289] [54096]

Intermittent hemodialysis
Administer acetaminophen every 8 hours.[32569]

Peritoneal dialysis
Administer acetaminophen every 8 hours.[32569]

Continuous renal replacement therapy (CRRT)
No dosage adjustment necessary.[32569]

†Off-label indication

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Administration Information

General Administration Information
For storage information, see the specific product information within the How Supplied section.

NOTE: Acute overdoses of acetaminophen are extremely toxic and potentially fatal. Do not exceed recommended daily dosage. In addition, ingestion of normal doses daily for many months has also been associated with hepatotoxicity and/or nephrotoxicity.

Route-Specific Administration

Oral Administration

- May be taken without regard to meals.

Oral Solid Formulations

- *Immediate-release tablets*: Administer with a sufficient amount of water.
- *Extended-release tablets*: Do not crush, chew, split, or dissolve in liquid.
- *Chewable tablets*: May be swallowed whole or chewed.
- *Oral granules*: Mix with a small amount of soft food (i.e., applesauce, ice cream, or jam) immediately prior to administration.
- *Oral powders*: Do not administer the capsules containing the powder whole. Open capsule and sprinkle over a small amount of water (< 5 ml) or mix with a small amount of soft food (i.e., applesauce, ice cream, or jam) immediately prior to administration.[54020]

Oral Liquid Formulations

- Liquid acetaminophen may be available in multiple concentrations. Always verify the concentration before administering each dose.
- For home administration, advise caregivers to administer the amount of medicine listed on the specific drug product label for the patient's weight and age or provide written instructions that specify the dose in milligrams (mg) and/or the concentration and the dose in milliliters (mL).

Oral solution:

- Administer using an oral calibrated measuring device to ensure accurate dosing.

Oral suspension:

- Shake well prior to each use.
- Administer using an oral calibrated measuring device to ensure accurate dosing.

Injectable Administration

- Visually inspect parenteral products for particulate matter and discoloration prior to administration whenever solution and container permit.
- To reduce the risk of dosing errors that can lead to accidental overdose, hepatotoxicity, and even death, use special care when preparing and administering acetaminophen intravenous injection. Specifically, ensure that:
  - the dose in milligrams (mg) and milliliters (mL) is not confused
  - weight-based dosing is used for patients weighing < 50 kg
  - infusion pumps are properly programmed
  - the total daily acetaminophen dose from all sources does not exceed recommended daily maximum limits [42289]

Intravenous Administration

Intermittent IV Infusion preparation:

- No further dilution of acetaminophen injectable solution is required.
- Do not add other medications to the vial or infusion device.
- For doses that are less than the amount of drug contained in a vial, the dose must be withdrawn from the vial using aseptic technique and placed in a separate empty, sterile container (e.g., glass bottle, plastic intravenous container, or syringe) prior to administration.
- For doses that are equal to the amount of acetaminophen contained in a single vial, a vented intravenous set may be used to deliver the dose directly from the vial.
- *Storage:* Acetaminophen vials are preservative free; discard any unused portion of the vial. Once the seal on the vial has been penetrated or the dose transferred to another container, the dose must be administered within 6 hours.[42289]

Intermittent IV Infusion Administration:

- Infuse the dose over 15 minutes.[42289]

Rectal Administration

- Instruct patient or caregiver on proper use of suppository.
- Prior to insertion, carefully remove the wrapper. Avoid excessive handling as to avoid melting of the suppository.
- If suppository is too soft to insert, chill in the refrigerator for 30 minutes or run cold water over it before removing the wrapper.
- Moisten the suppository with cool water prior to insertion.
- Have patient lie down on their side, usually in the Sim's lateral position to provide support and comfort.
- Apply gentle pressure to insert the suppository completely into the rectum, pointed end first, using a gloved, lubricated index finger.
- After insertion, keep the patient lying down to aid retention. May gently hold the buttock cheeks close together to keep the patient from immediately expelling the suppository. The suppository must be retained in rectum to ensure complete absorption.

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Contraindications / Precautions

Absolute contraindications are italicized

- *acetaminophen hypersensitivity*
- infection

- alcoholism
- bone marrow suppression
- breast-feeding
- children
- ethanol intoxication
- G6PD deficiency
- hepatic disease
- hepatitis
- hypovolemia
- immunosuppression
- infants
- malnutrition
- neonates
- neutropenia
- phenylketonuria
- B potential for overdose or poisoning
- pregnancy
- renal disease
- renal failure
- renal impairment
- tobacco smoking

Acetaminophen is contraindicated in patients with a known *acetaminophen hypersensitivity* or *hypersensitivity to any of the excipients* of the formulation to be used. Acetaminophen hypersensitivity reactions are rare, but severe sensitivity reactions are possible.

Intravenous (IV) acetaminophen is contraindicated in patients with *severe hepatic impairment* or *severe active hepatic disease*. Acetaminophen has the potential for overdose or poisoning causing acute liver failure, at times resulting in liver transplantation and death. Most cases of liver injury are associated with the use of acetaminophen at doses exceeding 4 grams per day and often involve the use of more than one acetaminophen-containing product. Caution must be used during the preparation and administration of IV acetaminophen, as well as the measurement of oral liquid dosage forms to minimize the risk of dosing errors that can result in accidental overdose. Advise patients receiving acetaminophen to carefully read OTC and prescription labels, to avoid excessive and/or duplicate medications, and to seek medical help immediately if more than 4 grams of acetaminophen is ingested in 1 day, even if they feel well. It is important to note that the risk of acetaminophen-induced hepatotoxicity is increased in patients with pre-existing hepatic disease (e.g., hepatitis), those who ingest alcohol (e.g., ethanol intoxication, alcoholism), those with chronic malnutrition, and those with severe hypovolemia. In patients with chronic hepatic disease, acetaminophen can be used safely in recommended doses and is often preferred to nonsteroidal anti-inflammatory drugs (NSAIDs) due to the absence of platelet impairment, gastrointestinal toxicity, and nephrotoxicity. Though the half-life of acetaminophen may be prolonged, repeated dosing does not result in drug or metabolite accumulation. In addition, cytochrome P450 activity is not increased and glutathione stores are not depleted in hepatically impaired patients taking therapeutic doses, therefore toxic metabolite formation and accumulation is not altered. Although it is always prudent to use the smallest dose of acetaminophen for the shortest duration necessary, courses less than 2 weeks in length have been administered safely to adult patients with stable chronic liver disease.[23562] [42289] [54020] [54066]

In patients with severe renal impairment or renal failure (CrCl <= 30 mL/min), dosage adjustment of intravenous acetaminophen may be required. [42289] Some studies have suggested an association between chronic use of acetaminophen and renal effects. The National Kidney Foundation states that there is negligible evidence to suggest chronic use of acetaminophen causes analgesic nephropathy; however, there is a weak association between chronic acetaminophen use and the prevalence of chronic renal failure and end stage renal disease.[54096] In a case-controlled study of adult patients with early renal failure, the regular use of acetaminophen (without aspirin) was associated with a risk of chronic renal failure that was 2.5-times as high as that for non-acetaminophen users. The risk increased with an increasing cumulative acetaminophen lifetime dose. The average dose used during periods of regular acetaminophen use also correlated with risk, as those who took >= 1.4 grams/day during periods of regular use had an odds ratio for chronic renal failure of 5.3; duration of therapy was unrelated to risk.[27368] The National Kidney Foundation considers acetaminophen as the non-narcotic analgesic of choice for episodic pain in patients with chronic renal disease, but discourages habitual consumption.[54096]

Patients with G6PD deficiency who overdose with acetaminophen may be at increased risk for drug-induced hemolysis. Practitioners should be aware of this potential complication and monitor at-risk patients for signs and symptoms of hemolysis. Conflicting data exists on whether therapeutic doses of acetaminophen can cause hemolysis in G6PD deficient patients. However, a direct cause and effect relationship has not been well established and therefore, therapeutic doses are generally considered safe in this population.[54061] [54063]

Symptoms of acute infection (e.g., fever, pain) can be masked during treatment with acetaminophen in patients with bone marrow suppression, especially neutropenia, or immunosuppression.

Tobacco smoking induces the cytochrome P450 isoenzyme CYP1A2 and may potentially increase the risk for acetaminophen-induced hepatotoxicity during overdose via enhanced generation of acetaminophen's hepatotoxic metabolite, N-acetyl-p-benzoquinonimine (NAPQI). In a retrospective chart review of 602 patients (13—86 years of age) admitted for acetaminophen toxicity, current daily tobacco use was registered in 70% of patients. Multivariant analyses found tobacco smoking to be an independent risk factor for hepatotoxicity, hepatic encephalopathy, and death. [28001] [28215]

Caution must be taken when administering acetaminophen to pediatric patients to ensure appropriate dosing. Liquid acetaminophen is available in multiple concentrations; verify the concentration before administering each dose. Other factors that can lead to inadvertent overdoses include substituting adult acetaminophen formulations for pediatric formulations for convenience, misreading or interpreting instructions, or administering more acetaminophen due to persistent fever.[25461] Repeated overdoses of acetaminophen in infants or children in combination with decreased nutrition may lead to changes in the metabolism of acetaminophen leading to hepatotoxicity. This combination leads to decreases in sulfation, glucuronidation and glutathione production. Safety and efficacy of IV acetaminophen has not been established in neonates, infants, or children < 2 years of age.[42289]

Intravenous acetaminophen is classified as a FDA pregnancy category C; no studies have been conducted in pregnant women or animals.[42289] All other formulations are FDA pregnancy category B. Acetaminophen does cross the placenta and should be used during pregnancy only if the benefits to the mother outweigh the potential risks to the fetus or infant. No overall increase in fetal mortality, determined by pregnancy outcomes of mothers that overdosed on various amounts of oral acetaminophen, was apparent amongst 300 women.[27731] Treatment with acetylcysteine or methionine did not appear to affect fetal or neonatal toxicity. Of 235 infants exposed to an overdose of only acetaminophen, 168 were normal, 8 had malformations, 16 were spontaneously aborted, and 43 were electively terminated. None of the infants with malformations were exposed during the first trimester, but all of the spontaneous abortions were subsequent to first trimester exposure.

According to manufacturers, acetaminophen should be used during breast-feeding only if the benefits to the mother outweigh the potential risks to the infant. Acetaminophen crosses into breast milk, with a concentration ranging from 0.1—1.85% of the maternal dose. According to the American Academy of Pediatrics (AAP), acetaminophen has not been associated with any observable changes in nursing infants of mothers that took acetaminophen while breast-feeding. The AAP and other experts regard acetaminophen as a maternal medicine that is usually compatible with breast-feeding[27500] According to the manufacturer, intravenous acetaminophen should be used cautiously in breast-feeding mothers.[42289] Consider the benefits of breast-feeding, the risk of potential infant drug exposure, and the risk of an untreated or inadequately treated condition. If a breast-feeding infant experiences an adverse effect related to a maternally ingested drug, healthcare providers are encouraged to report the adverse effect to the FDA.

Some, but not all, acetaminophen products (particularly certain chewable tablets) contain aspartame and should be used with caution in patients with phenylketonuria, since aspartame is a source of phenylalanine. Consult specific product labeling for inactive ingredient content.

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Pregnancy / Breast-feeding

Intravenous acetaminophen is classified as a FDA pregnancy category C; no studies have been conducted in pregnant women or animals.[42289] All other formulations are FDA pregnancy category B. Acetaminophen does cross the placenta and should be used during pregnancy only if the benefits to the mother outweigh the potential risks to the fetus or infant. No overall increase in fetal mortality, determined by pregnancy outcomes of mothers that overdosed on various amounts of oral acetaminophen, was apparent amongst 300 women.[27731] Treatment with acetylcysteine or methionine did not appear to affect fetal or neonatal toxicity. Of 235 infants exposed to an overdose of only acetaminophen, 168 were normal, 8 had malformations, 16 were spontaneously aborted, and 43 were electively terminated. None of the infants with malformations were exposed during the first trimester, but all of the spontaneous abortions were subsequent to first trimester exposure.

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Interactions

Level 1 - Severe

Level 2 - Major

- Acetaminophen
- Aprepitant, Fosaprepitant
- Ethanol
- Imatinib, STI-571
- Isoniazid, INH
- Lamotrigine

Level 3 - Moderate

- Busulfan
- Cholestyramine
- Dasabuvir; Ombitasvir; Paritaprevir; Ritonavir
- Diflunisal
- Ombitasvir; Paritaprevir; Ritonavir
- Osimertinib
- Rifabutin
- Rifampin
- Salicylates
- tobacco

Level 4 - Minor

- Antacids
- Barbiturates
- Carbamazepine
- Charcoal
- Echinacea
- Ethotoin
- Exenatide
- Fosphenytoin
- Oxcarbazepine
- Phenytoin
- Prilocaine
- St. John's Wort, Hypericum perforatum
- Sulfinpyrazone
- Warfarin
- Zidovudine, ZDV

NOTE: Although acetaminophen is primarily metabolized via glucuronidation and sulfate conjugation, it is also a substrate of CYP2E1 and CYP1A2. Drugs that induce these enzymes may increase the metabolism of acetaminophen to its toxic metabolite and the risk of hepatotoxicity.[42289]

Many prescription and non-prescription medicines contain acetaminophen. Avoid concurrent use of products that contain acetaminophen as the maximum daily dose (i.e., 4 g/day for adults; 75 mg/kg/day for infants and children) may be exceeded leading to an increased risk of hepatotoxicity. Also, high dosages of acetaminophen on a chronic basis can cause depletion of glutathione stores, which can lead to a greater production of the hepatotoxic metabolite, NAPQI.[4925] Advise patients to carefully read the ingredients of any other products they are taking with acetaminophen.

The risk of developing hepatotoxicity from acetaminophen appears to be increased in patients who regularly consume ethanol. In these patients, hepatotoxicity is possible even at normal, therapeutic dosages of acetaminophen.[1654] Acute or chronic ethanol use increases acetaminophen-induced hepatotoxicity by inducing cytochrome P450 (CYP) 2E1 leading to increased formation of the hepatotoxic metabolite of acetaminophen. [583] Also, chronic alcohol use can deplete liver glutathione stores. Administration of acetaminophen should be limited or avoided altogether in patients with alcoholism or patients who consume ethanol regularly (see Acetaminophen Contraindications).[4934]

Drugs that induce the hepatic isoenzymes CYP2E1 and CYP1A2, such as carbamazepine, oxcarbazepine, barbiturates (including primidone), and phenytoin or fosphenytoin (and possibly ethotoin), may potentially increase the risk for acetaminophen-induced hepatotoxicity via generation of a greater percentage of acetaminophen's hepatotoxic metabolite, NAPQI. [4718] [4939] Also, the analgesic activity of acetaminophen may be reduced. Acetaminophen-related hepatotoxicity has occurred clinically with the concurrent use of acetaminophen 1000 mg daily and phenobarbital 100 mg daily [107] and with acetaminophen 1300—6200 mg daily and phenytoin.[4927] In both cases, acetaminophen cessation led to serum transaminase normalization within 2 weeks.[107] [4927]

The combination of isoniazid, INH and acetaminophen has caused severe hepatotoxicity.[4930] [4931] Isoniazid, while present in the body, induces the hepatic cytochrome P450 isoenzyme 2E1.[3733] In slow N-acetylators, induction of 2E1 occurs for about 2 weeks after INH clearance by the body. Induction of 2E1 activity may potentially increase the risk for acetaminophen-induced hepatotoxicity via enhanced generation of acetaminophen's hepatotoxic metabolite, NAPQI.[3733] Concomitant use of INH and acetaminophen when given at the same time resulted in a markedly decreased formation clearance for NAPQI in patients who received INH daily for 6 months. However, decreased formation clearance for NAPQI only persisted in slow acetylators when acetaminophen was administered 12 hours after INH administration. Rapid acetylators had enhanced formation of NAPQI.[4932] Thus, the timing of acetaminophen administration and whether a person is a fast or slow acetylator appears to affect the likelihood of acetaminophen hepatotoxicity.

As cytochrome P450 isoenzyme inducers, rifampin and rifabutin could induce the metabolism of acetaminophen, altering the clinical response. An increase in acetaminophen-induced hepatotoxicity may be seen by increasing the metabolism of acetaminophen to its toxic metabolite, NAPQI. [4718] Also, the analgesic activity of acetaminophen may be reduced. Hepatic failure and encephalopathy has been attributed to the combination of rifampin and acetaminophen.[4929] A 32 year-old female with normal prothrombin time and liver function developed a serum alanine transaminase concentration of 450 IU, an international normalized ratio of 5.2, confusion, and agitation 2 days after starting rifampicin 600 mg twice daily. She had been taking 2—4 grams of acetaminophen on a daily basis for several weeks. Her liver dysfunction resolved with rifampicin and acetaminophen withdrawal and vitamin K and N-acetylcysteine administration.[4929]

Sulfinpyrazone can induce hepatic oxidative microsomal enzymes and the drug has been shown to increase acetaminophen clearance by roughly 23%.[4939] Theoretically, it is thought that the induction of acetaminophen metabolism by sulfinpyrazone may increase the risk of acetaminophen hepatotoxicity due to the formation of increased amounts of toxic acetaminophen metabolites, but there is no confirmatory evidence.

Prolonged concurrent use of acetaminophen and salicylates is not recommended. High-dose, chronic administration of the combined analgesics significantly increases the risk of analgesic nephropathy, renal papillary necrosis, and end-stage renal disease. In a case-controlled study of patients with early renal failure, the regular use of aspirin and acetaminophen was associated with an odds ratio of 2.2 (95% confidence interval 1.4 to 3.5) when regular aspirin users were the reference group.[4064] The trend toward greater risk with an increasing cumulative life-time dose of acetaminophen was statistically significant with a risk that was 2.4-times as high for subjects who had consumed a total > 500 g of acetaminophen in combination with aspirin than for those who had used aspirin alone. Do not exceed the recommended individual maximum doses when these agents are given concurrently for short-term therapy.

Acetaminophen is routinely considered safer than aspirin and is the agent of choice when a mild analgesic/antipyretic is necessary for a patient receiving therapy with warfarin. However, acetaminophen has also been shown to augment the hypoprothrombinemic response to warfarin. Both

INR prolongation and clinical bleeding have been reported. Concomitant acetaminophen ingestion with warfarin may increase the INR in a dose-related fashion.[1628] The exact mechanism of this interaction is not known. Acetaminophen and R-warfarin are both metabolized by the cytochrome P450 (CYP)1A2 and CYP3A4 isoenzymes to varying degrees. In some patients, metabolism of acetaminophen may be shifted towards CYP1A2 and CYP3A4 due to genetic polymorphism of CYP2E1 resulting in the decreased metabolism of R-warfarin; although, this mechanism is theoretical.[2678] Single doses or short courses (i.e., several days) of treatment with acetaminophen are probably safe in most patients taking warfarin. Clinicians should be alert for an interaction with warfarin if acetaminophen is co-administered daily in large doses (> 1.3 g/day) for longer than 10—14 days. Careful monitoring of a patient's INR is recommended after initiation and cessation of acetaminophen.

Use of acetaminophen prior to (< 72 hours) or concurrently with busulfan may result in decreased clearance of busulfan due to acetaminophen-induced decreases in glutathione levels.[4749] Busulfan is metabolized in the liver through conjugation with glutathione, which is catalyzed by glutathione S-transferase. During high-dose busulfan treatment, glutathione hepatocellular concentrations may be depleted. As the hepatotoxic metabolite of acetaminophen, NAPQI, is inactivated by conjugation with glutathione, the risk of acetaminophen-related hepatotoxicity may be increased.[4943]

Acetaminophen plasma concentrations can increase by approximately 50% following administration of diflunisal. Acetaminophen has no effect on diflunisal concentrations. Acetaminophen has been associated with severe hepatotoxic reactions (see Acetaminophen Adverse Reactions); therefore, caution should be exercised when using these agents concomitantly[5099]

Prilocaine and acetaminophen each individually can cause methemoglobinemia. Patients treated with prilocaine who are receiving acetaminophen concurrently are at greater risk for developing methemoglobinemia.[5100]

Acetaminophen can be hepatotoxic (see Adverse Reactions), and lamotrigine appears to be a potential cause of progressive and fatal hepatotoxicity despite drug discontinuation. A 35 year-old developed fulminant liver failure possibly caused by lamotrigine. She was taking several other drugs including acetaminophen.[5101] In a randomized, single-dose study, the serum half-life of lamotrigine after a 300 mg dose decreased by 15% and the area under the plasma concentration-time curve decreased by 20% when given with acetaminophen 900 mg 3 times a day as compared with administration of lamotrigine with placebo. As the lamotrigine maximum serum concentration (Cmax) and time to Cmax was similar between the groups, and the lamotrigine renal clearance increased by 7%, acetaminophen appears to enhance removal of lamotrigine from the circulation.[5102]

Imatinib, STI-571 may affect the metabolism of acetaminophen. In a phase II trial, one death due to liver failure occurred within 12 days of beginning imatinib 600 mg/day.[4966] The patient had been receiving acetaminophen 3000—3500 mg daily for approximately 1 month. After 6 days of imatinib, the patient developed upper quadrant discomfort, jaundice, hyperbilirubinemia and elevated serum transaminase concentrations. Although imatinib was stopped on day 7 and tests for infection were negative, the patient's condition deteriorated.[4800] The mechanism of the possible interaction between imatinib and acetaminophen has not been elucidated. No studies examining the potential interaction have been performed. Patients should be warned to limit their use of acetaminophen, including non-prescription products, while taking imatinib; chronic acetaminophen therapy should be avoided.

St. John's wort, Hypericum perforatum induces cytochrome P450 1A2.[4935] About 10—15% of the acetaminophen dose undergoes oxidative metabolism via cytochrome P450 isoenzymes (CYP) 2E1 (major pathway), 3A4, and 1A2, which produces the hepatotoxic metabolite, N-acetyl-p-benzoquinonimine (NAPQI).[2678] Thus, theoretically St. John's wort might increase the risk of acetaminophen-induced hepatotoxicity by increasing the metabolism of acetaminophen to NAPQI.[4935]

Both acetaminophen and zidovudine, ZDV undergo glucuronidation. Competition for the metabolic pathway is thought to have caused a case of acetaminophen-related hepatotoxicity. Data suggest that acetaminophen glucuronidation is competitively inhibited by zidovudine, whereas zidovudine glucuronidation is only slightly inhibited by acetaminophen. As more acetaminophen is oxidized, glutathione reserves are needed to detoxify the hepatotoxic intermediate, NAPQI. Thus, the interaction may be more clinically significant in patients with depleted glutathione stores, such as patients with acquired immunodeficiency syndrome, poor nutrition, or alcoholism. Also, patients taking an inducer of 2E1 or 1A2 with zidovudine and acetaminophen will have greater production of NAPQI and thus, a greater likelihood of hepatotoxicity.[4928]

Tobacco smoking induces the cytochrome P450 isoenzyme CYP1A2 [4718] and may potentially increase the risk for acetaminophen-induced hepatotoxicity during overdose via enhanced generation of acetaminophen's hepatotoxic metabolite, NAPQI. In one study, current tobacco smoking was found to be very frequent in patients admitted with acetaminophen poisoning. Tobacco smoking appears to be an independent risk factor of severe hepatotoxicity, acute liver failure and death following acetaminophen overdose.[4940]

Cholestyramine has also been shown to decrease the absorption of acetaminophen by roughly 60%. Experts have recommended that cholestyramine not be given within 1 hour of acetaminophen if analgesic or antipyretic effect is to be achieved.[4944] The bile-acid sequestrant cholestyramine is well-known to cause drug interactions by binding and decreasing the oral administration of many drugs; to minimize drug interactions, the manufacturer recommends administering other drugs at least 1 hour before or at least 4—6 hours after the administration of cholestyramine.[4793]

Activated charcoal binds many drugs within the gut and is often therapeutically employed in the setting of acetaminophen overdose. Charcoal appears to bind acetaminophen more avidly than the orally-administered antidotes (acetylcysteine) employed in such poisoning[219]; thus, coadministration of charcoal does not preclude the administration of such antidotes in the setting of acetaminophen overdose. However, since

activated charcoal is available as a dietary supplement, patients should be aware that administering charcoal at the same time as a routine acetaminophen dosage would be expected to interfere with the analgesic and antipyretic efficacy of acetaminophen.[4944]

Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.[6086]When 1000 mg acetaminophen elixir was given with 10 mcg exenatide (at 0 hours) and at 1, 2 and 4 hours after exenatide injection, acetaminophen AUCs were decreased by 21%, 23%, 24%, and 14%, respectively; C_{max} was decreased by 37%, 56%, 54%, and 41%, respectively. Additionally, acetaminophen T_{max} was increased from 0.6 hours in the control period to 0.9, 4.2, 3.3, and 1.6 hours, respectively. Acetaminophen AUC, C_{max} and T_{max} were not significantly changed when acetaminophen was given 1 h before exenatide injection.[8017] The mechanism of this interaction is not available (although it may be due to delayed gastric emptying) and the clinical impact has not been assessed. To avoid potential pharmacokinetic interactions that might alter analgesic effectiveness of acetaminophen, patients should take acetaminophen at least one hour prior to exenatide SQ injection.

Although rare, hepatotoxicity has been reported with echinacea use. A proposed mechanism for the hepatotoxicity associated with echinacea is that some species may contain pyrrolizidine alkaloids; pyrrolizidine alkaloids deplete glutathione, which may increase the risk of liver toxicity, especially when used in conjunction with acetaminophen. The significance of echinacea-induced hepatotoxicity has been challenged as echinacea does not contain the 1,2 unsaturated necrine ring system that is typically associated with pyrrolizidine alkaloid hepatotoxicity. The hepatoxicity could be derived from contaminants, rather than the herb itself. Irregardless, clinicians and patients should monitor for signs of hepatoxicity if these drugs are coadministered.[8892] [5314]

Concurrent administration of acetaminophen with ombitasvir; paritaprevir; ritonavir may result in elevated acetaminophen plasma concentrations and subsequent adverse events. Acetaminophen is metabolized by the hepatic isoenzyme CYP3A4; ritonavir is an inhibitor of this enzyme. Caution and close monitoring are advised if these drugs are administered together.[60002] [28100] [25460]

Concurrent administration of acetaminophen with dasabuvir; ombitasvir; paritaprevir; ritonavir may result in elevated acetaminophen plasma concentrations and subsequent adverse events. Acetaminophen is metabolized by the hepatic isoenzyme CYP3A4; ritonavir is an inhibitor of this enzyme. Caution and close monitoring are advised if these drugs are administered together.[58664] [28100] [25460]

Use caution if acetaminophen and aprepitant, fosaprepitant are used concurrently and monitor for an increase in acetaminophen-related adverse effects for several days after administration of a multi-day aprepitant regimen. Acetaminophen is a minor (10 to 15%) substrate of CYP3A4. Aprepitant, when administered as a 3-day oral regimen (125 mg/80 mg/80 mg), is a moderate CYP3A4 inhibitor and inducer; substitution of fosaprepitant 115 mg IV on day 1 of the 3-day regimen may lessen the inhibitory effects of CYP3A4. The AUC of a single dose of another CYP3A4 substrate, midazolam, increased by 2.3-fold and 3.3-fold on days 1 and 5, respectively, when coadministered with a 5-day oral aprepitant regimen. After a 3-day oral aprepitant regimen, the AUC of midazolam increased by 25% on day 4, and decreased by 19% and 4% on days 8 and 15, respectively, when given on days 1, 4, 8, and 15. As a single 40-mg oral dose, the inhibitory effect of aprepitant on CYP3A4 is weak, with the AUC of midazolam increased by 1.2-fold; the midazolam AUC increased by 1.5-fold after a single 125-mg dose of oral aprepitant. After single doses of IV fosaprepitant, the midazolam AUC increased by 1.8-fold (150 mg) and 1.6-fold (100 mg); less than a 2-fold increase in the midazolam AUC is not considered clinically important. After administration, fosaprepitant is rapidly converted to aprepitant and shares the same drug interactions. [30676] [40027] [28100] [25460]

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Adverse Reactions

- abdominal pain
- acute generalized exanthematous pustulosis (AGEP)
- agitation
- agranulocytosis
- anaphylactic shock
- anaphylactoid reactions
- anemia
- angioedema
- anorexia
- anxiety
- constipation
- contact dermatitis
- diarrhea
- dyspnea
- elevated hepatic enzymes
- erythema
- exfoliative dermatitis
- fatigue
- hypotension
- hypoxia
- injection site reaction
- insomnia
- interstitial nephritis
- jaundice
- maculopapular rash
- malaise
- muscle cramps
- musculoskeletal pain
- myocarditis
- nausea
- neutropenia
- oliguria
- pancytopenia
- peripheral edema
- pleural effusion
- pruritus
- pulmonary edema

- fever
- headache
- hearing loss
- heart failure
- hemolysis
- hemolytic anemia
- hepatic encephalopathy
- hepatic failure
- hepatic necrosis
- hypertension
- hypervolemia
- hypoalbuminemia
- hypokalemia
- hypomagnesemia
- hypophosphatemia
- hypoprothrombinemia
- purpura
- rash (unspecified)
- renal failure (unspecified)
- renal papillary necrosis
- renal tubular necrosis
- rhabdomyolysis
- sinus tachycardia
- Stevens-Johnson syndrome
- thrombocytopenia
- thrombocytosis
- toxic epidermal necrolysis
- trismus
- urticaria
- vomiting
- wheezing

Headache can occur after acetaminophen administration. In clinical trials of adult patients receiving IV acetaminophen, headache occurred in 10% of patients compared to 9% of those receiving placebo. Headache was also reported in clinical trial of IV acetaminophen in pediatric patients.[42289] Overuse of acetaminophen by headache-prone patients frequently produces drug-induced rebound headache or medication overuse headache that is accompanied by dependence on symptomatic medication, tolerance (refractoriness to prophylactic medication), and withdrawal symptoms. When increasing doses of analgesia are required, the cause may be multi-factorial, including tolerance, progression of disease or psychologic distress. Overuse of acetaminophen (i.e., simple analgesic) has been defined as taking 3 or more doses per day more often than 5 days per week.[27347] The frequency of use may be more important than the dose. Features of a rebound headache include morning headache, end-of-dosing interval headache, or headache improvement with discontinuation of overused medication. Stopping the symptomatic medication may result in a period of increased headache and then headache improvement. Analgesic overuse may be responsible for the transformation of episodic migraine or episodic tension headache into daily headache and may perpetuate the syndrome.[27347]

Gastrointestinal adverse events, such as nausea, vomiting, constipation, and diarrhea may occur after parenteral acetaminophen administration. The most common gastrointestinal side effects reported in clinical trials of IV acetaminophen in adults were nausea, occurring in 34% of patients who received acetaminophen versus 31% of those who received placebo, and vomiting, occurring in 15% of the acetaminophen group versus 11% of those who received placebo. Gastrointestinal side effects in pediatric patients receiving IV acetaminophen in clinical trials also included nausea and vomiting, as well as constipation (>= 5% of patients). Diarrhea and abdominal pain were also reported in pediatric patients.[42289] Oral therapy is not usually associated with significant adverse effects in usual and prudent use as recommended. If a patient who has taken oral acetaminophen presents with significant gastrointestinal symptoms (e.g., nausea, vomiting, and abdominal pain), acetaminophen-induced hepatotoxicity should be considered (see hepatic effects).

Acetaminophen is a leading cause of hepatic adverse effects. Clinical trials of IV acetaminophen in adults and pediatric patients who received the manufacturer recommended dose have reported increases in aspartate aminotransferase and other hepatic enzyme elevations.[42289] A 2009 report of the FDA reported that based on combined data from 22 specialty medical centers in the United States, acetaminophen-related liver injury was the leading cause of acute hepatic failure for the years 1998 through 2003.[44683] While many cases are the result of intentional overdosage, many other cases occur due to unintentional overdose with these products. Maximum recommended doses for acetaminophen should not be exceeded in acute or chronic use. A metabolite of acetaminophen, N-acetyl-para-benzoquinoneimine (NAPQI), is hepatotoxic. The amount of NAPQI production and exposure is limited in patients with normal hepatic function that take recommended dosages (see Pharmacokinetics). Excessive acetaminophen exposure saturates the sulfation pathway and can lead to greater NAPQI exposure. Also, induction of the oxidative pathway by ethanol or other drugs may result in a greater fraction of the acetaminophen dose being converted to NAPQI (see Drug Interactions). Lastly, malnutrition and chronic ethanol use can cause depletion of glutathione and sulfate hepatic stores, which can result in greater NAPQI exposure. In most cases, acetaminophen hepatotoxicity occurs as a result of an acute overdose; however, moderately excessive doses, if taken chronically, can also produce hepatotoxicity. Furthermore, idiosyncratic reactions have been noted. Acetaminophen-induced hepatotoxicity is manifested as hepatic necrosis, jaundice, and hepatic encephalopathy. Nausea/vomiting, anorexia, abdominal pain, and malaise usually occur within 2—3 hours after ingestion of toxic doses. Elevated hepatic enzymes and hypoprothrombinemia are seen, and bleeding may occur. After acute overdose, 2 or 3 days pass before maximum liver damage and hepatic failure becomes apparent. GI bleeding can occur secondary to low prothrombin levels. Administration of intravenous vitamin K is recommended for hypoprothrombinemia due to acetaminophen overdosage. Recovery may occur within 5—10 days. Young children appear to be at less risk of developing hepatotoxicity, possibly because of an age-related difference in the metabolism of the drug. It has also been suggested that recent fasting is associated with hepatotoxicity in patients taking higher than recommended doses.[24018] Prompt oral administration of N-acetylcysteine, which serves as a substitute sulfhydryl donor for glutathione, is the recommended treatment for an acute acetaminophen overdose if the ingested acetaminophen dose is at least 140 mg/kg or in other applicable situations, such as ongoing hepatic damage likely due to recent acetaminophen ingestion. Obtain immediate and daily serum transaminase concentrations. Serum acetaminophen concentrations that are obtained at least 4 hours after acetaminophen ingestion help predict toxicity; however, do not delay acetylcysteine administration for serum acetaminophen concentration results.

Acetaminophen can rarely cause acute renal tubular necrosis and chronic analgesic nephropathy, which is characterized by interstitial nephritis and renal papillary necrosis, in patients receiving high doses (e.g., 2.5—10 g/day for adults) chronically or after acute overdose. Acute renal failure (unspecified) may occur in 25—30% of patients who have acetaminophen-induced hepatotoxicity. Rarely, acute renal failure may occur without

severe hepatic toxicity. The risk of renal complications appears to be higher in patients with alcoholism. Chronic acetaminophen use has been implicated as a contributing factor in the decline of renal function in patients with underlying renal disease, including diabetic nephropathy.[23977] Oliguria has also been reported in clinical trials of pediatric patients receiving IV acetaminophen.[42289]

Hypokalemia and peripheral edema occurred in at least 1% of patients in clinical trials of both adult and pediatric patients treated with IV acetaminophen. Other metabolic disturbances reported in at least 1% of pediatric patients after administration of IV acetaminophen included hypoalbuminemia, hypomagnesemia, hypophosphatemia, and hypervolemia.[42289]

Cardiovascular adverse events reported in clinical trials of IV acetaminophen in at least 1% of adult and pediatric patients include both hypertension and hypotension. Sinus tachycardia was also reported in pediatric patients.[42289]

Anemia (>= 1%) and fever (>= 1%) have been reported during pediatric clinical trials of IV acetaminophen. In addition, sporadic case reports of agranulocytosis, thrombocytopenia, thrombocytosis, neutropenia, and pancytopenia have been described in patients taking acetaminophen. Symptoms such as unusual tiredness or weakness, unusual bleeding or bruising, and unexplained sore throat or fever should be investigated promptly.[31419] [31420] [42289] [54020] Acetaminophen sulfate, a metabolite of acetaminophen, may rarely cause immune-mediated thrombocytopenia.[31419] Symptoms such as unusual tiredness or weakness, unusual bleeding or bruising, and unexplained sore throat or fever should be investigated promptly.

Drug-induced hemolysis and hemolytic anemia have been associated with acetaminophen overdose in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Though several case reports of hemolytic anemia in G6PD-deficient patients receiving therapeutic doses of acetaminophen exist, a direct cause and effect relationship has not been well established. G6PD-deficient patients presenting with acetaminophen toxicity should be monitored closely for signs and symptoms of hemolysis.[54061] [54063]

Dermatological adverse reactions of varying severity have been reported after acetaminophen administration, including the rare but serious skin reactions Stevens-Johnson syndrome, toxic epidermal necrolysis, and acute generalized exanthematous pustulosis (AGEP). These reactions may occur at any time during treatment and in patients who have taken acetaminophen previously with no reaction. Stevens-Johnson syndrome and toxic epidermal necrolysis may begin with flu-like symptoms, followed by skin rash and blistering producing extensive damage. Blindness and internal organ damage may also occur which can be fatal.[55541] [55544] Acute generalized exanthematous pustulosis (AGEP) is characterized by acute onset, fever, and nonfollicular pustules on a erythematous rash, and typically resolves within 2 weeks following drug discontinuation.[27736] [55544] From 1969—2012, 107 cases of serious skin reactions associated with acetaminophen use were reported to the FDA, resulting in 67 hospitalizations and 12 deaths.[55544] Toxic epidermal necrolysis (TEN) occurred in a 7 year old girl after she took 3 doses of oral acetaminophen to treat a fever and sore throat. Twelve hours after the last dose, an erythematous rash appeared, which became generalized and vesicular over the next few hours. The patient developed a fever, low blood pressure, and an elevated erythrocyte sedimentation rate and liver function tests. Skin biopsy was positive for subepidermal blister formation with full-thickness necrolysis of the epidermis. Acetaminophen re-challenge, performed 6 months later in an allergy clinic, produced similar symptoms within 30 minutes of administration and confirmed the initial diagnosis.[27732] Pruritus and rash (unspecified) were reported in pediatric patients during clinical trials of IV acetaminophen. Other hypersensitivity reactions may be manifested by urticaria, erythema, maculopapular rash, and fever. Though rare, anaphylactic shock, angioedema, and anaphylactoid reactions have been reported.[42289] [54020] Multiple cases of allergic contact dermatitis (delayed hypersensitivity type) have been reported in the literature. Various reactions, including generalized pruriginous micropapular eruption, facial edema, generalized pruriginous exanthem, exfoliative dermatitis, and generalized exanthema occurred within several hours after ingestion.[27734] [27735] Patients who develop allergic or hypersensitivity reactions should discontinue acetaminophen immediately and seek medical attention for symptomatic treatment.

A case of acquired purpura fulminans developed in a 32 year old woman who was instructed to take acetaminophen 1000 mg every 4—6 hours as needed for pain. The patient noted rapidly spreading purpuric lesions and associated edema. Her lesions were nonblanchable and enlarging, and she had multiple purplish-black hemorrhagic and necrotic areas. Purpura fulminans is usually associated with disseminated intravascular coagulation and can occur in patients with inherited or acquired deficiencies of the protein C anticoagulant pathway. Based on the patient's history of alcohol use and poor nutritional status, the authors concluded that reduced hepatic glutathione stores were further reduced by the introduction of acetaminophen, leading to impaired protein C and S synthesis and propagation of the disseminated intravascular coagulation cascade. Discontinuation of alcohol and acetaminophen and administration of vitamin K, heparin, and a systemic antibiotic led to almost complete purpuric lesion and hepatotoxicity resolution in 6 days.[27733]

Insomnia occurred in 7% of adult patients who received IV acetaminophen in clinical trials versus 5% of those who received placebo. Anxiety and fatigue also occurred in adult patients treated with IV acetaminophen. In clinical trials of pediatric patients receiving IV acetaminophen, agitation was one of the more common adverse events, occurring in >= 5% of patients. Insomnia was also reported in pediatric patients.[42289]

Respiratory adverse effects seen after administration of IV acetaminophen in at least 1% of adults in pre-marketing clinical trials included dyspnea and abnormal breath sounds. Atelectasis (>= 5%) was the most common respiratory effect reported in pediatric clinical trials of IV acetaminophen. In addition, pulmonary edema, hypoxia, pleural effusion, stridor, and wheezing were reported in >= 1% of pediatric patients.[42289] There is epidemiological evidence in children and adults associating acetaminophen use with asthma symptoms. In addition, evidence suggests in utero and early infancy exposure may be associated with an increased risk of childhood asthma. Researchers hypothesize that acetaminophen may contribute to asthma through depletion of airway mucosal glutathione, increasing oxidative stress, epithelial damage, and airway inflammation.[54102] [54104] [54107]

Muscle cramps or spasms occurred in both adult and pediatric patients treated with IV acetaminophen in clinical trials. Other musculoskeletal events included trismus in adult patients and pain in the extremities (musculoskeletal pain) in pediatric patients.[42289] Acetaminophen-induced rhabdomyolysis has been described in a single case report. A 17 year old male with a past medical history of drug-induced reactions (hepatitis, agranulocytosis, desquamative dermatitis, and pyrexia) after receiving acetaminophen with or without concurrent antibiotics, was re-challenged with oral acetaminophen 400 mg. Within 5 hours of administration, the adolescent presented with febrile exanthema, neutropenia, and increased C-reactive protein, creatine phosphokinase, tumor necrosis factor-alpha, interleukin-6, and interleukin-10; the skin eruption and fever lasted 36 hours. Symptoms such as unusual tiredness, weakness or unusual pain and swelling of the extremities, nausea and vomiting, and dark-colored urine should be investigated promptly.[31420]

Myocyte injury was reported in a 15-year-old female. She developed fatal heart failure due to toxic myocarditis after an unspecified intentional overdose of acetaminophen.[31421]

Prospective studies have shown there to be a slight but consistent association between regular analgesic use and hearing loss. Acetaminophen related ototoxicity may result from depletion of glutathione, which protects the cochlea from noise damage.[53720] As a true long-term association may exist, counsel patients to minimize long-term treatment with acetaminophen as much as possible.A prospective analysis examining the association between analgesic use and the risk of hearing loss was conducted in 62,261 women 31—48 years of age at study enrollment who were originally enrolled in the Nurses' Health Study II. The association between self-reported hearing loss and analgesic use (including acetaminophen, aspirin, and NSAIDs) was examined over 14 years. During 764,247 person-years of follow-up, 10,012 cases of hearing loss were reported. After adjustment for confounders, acetaminophen use >= 2 days per week was independently associated with an increased risk of hearing loss, with the relative risk of hearing loss increasing with increasing frequency of use. Acetaminophen use 2—3, 4—5, or >= 6 days per week was associated with relative risks of 1.11 (95% CI 1.02—1.19), 1.21 (95% CI 1.07—1.37), and 1.08 (95% CI 0.95—1.22), respectively, with a p trend of 0.0007. Of note, those with more frequent use of acetaminophen had higher body mass indices; were more likely to smoke, have hypertension, or have diabetes; and were less physically active.[53720] In a similar study in male patients, the association between professionally diagnosed hearing loss and analgesic use (including acetaminophen, aspirin, and NSAIDs) was prospectively analyzed in 26,917 patients 40—74 years of age at study enrollment over 18 years. During 369,079 person-years of follow-up, 3488 cases of hearing loss were reported. After adjustment for confounders, the hazard ratio (HR) for acetaminophen associated hearing loss was 1.22 (95% CI 1.07—1.39, p = 0.09) in patients who were regular users of the drug (>= 2 times weekly) compared to those with less use. Men who regularly used acetaminophen for >= 4 years were 33% (14—56%) more likely to develop hearing loss than those with shorter use. In men < 50 years, the HR of hearing loss was 1.99 (95% CI 1.34—2.95); the degree of association generally decreased with aging.[53719] These studies do suggest association; however, data are based on patient reporting of the outcomes. Information regarding noise exposure and analgesic doses was not provided.[53719] [53720]

An injection site reaction, described as infusion site pain, occurred in >= 1% of patients receiving IV acetaminophen during clinical trials.[42289]

Revision Date: 6/12/2015 12:38:00 PM

How Supplied

Acetaminophen Chewable tablet

Acetaminophen 160mg Chewable Tablet (52735-0754) (Family Pharmacy)
Acetaminophen 160mg Tablet (00536-3284) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)
Acetaminophen 80mg Chewable Tablet (00364-0643) (Actavis Inc. formerly Watson Pharmaceuticals Inc) (off market)
Acetaminophen 80mg Chewable Tablet (65162-0603) (Akyma Pharmaceuticals) (off market)
Acetaminophen 80mg Chewable Tablet (24385-0481) (AmerisourceBergen Corporation)
Acetaminophen 80mg Chewable Tablet (24385-0492) (AmerisourceBergen Corporation)
Acetaminophen 80mg Chewable Tablet (00761-0916) (Basic Vitamins) (off market)
Acetaminophen 80mg Chewable Tablet (00761-0917) (Basic Vitamins) (off market)
Acetaminophen 80mg Chewable Tablet (17236-0603) (Dixon Shane Inc) (off market)
Acetaminophen 80mg Chewable Tablet (52735-0705) (Family Pharmacy)
Acetaminophen 80mg Chewable Tablet (52735-0726) (Family Pharmacy)
Acetaminophen 80mg Chewable Tablet (53746-0020) (Interpharm Inc) (off market)
Acetaminophen 80mg Chewable Tablet (00820-0145) (Logen Pharmaceuticals Inc.) (off market)
Acetaminophen 80mg Chewable Tablet (11845-0849) (Mason Vitamins)
Acetaminophen 80mg Chewable Tablet (49348-0199) (McKesson Drug Company)

Acetaminophen 80mg Chewable Tablet (00084-0419) (Natural Nutritionals Company) (off market)

Acetaminophen 80mg Chewable Tablet (00084-0426) (Natural Nutritionals Company) (off market)

Acetaminophen 80mg Chewable Tablet (69618-0012) (Reliable 1 Laboratories LLC)

Acetaminophen 80mg Chewable Tablet (00122-0868) (Rexall Group) (off market)

Acetaminophen 80mg Chewable Tablet (00122-0873) (Rexall Group) (off market)

Acetaminophen 80mg Chewable Tablet (60814-0144) (Rexall Group) (off market)

Acetaminophen 80mg Chewable Tablet (60814-0145) (Rexall Group) (off market)

Acetaminophen 80mg Chewable Tablet (11383-0142) (Weeks and Leo)

Children's Acetaminophen 80mg Chewable Tablet (00536-3233) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)

Children's Genapap Chewable Tablet (Grape) (00182-2147) (Ivax Corporation a Division of Teva USA)

Children's Pain and Fever 80mg Chewable Tablet (00536-3234) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)

GoodSense Acetaminophen 80mg Chewable Tablet (00113-0481) (Goodsense a Division of Perrigo)

Leader Children's Pain Reliever Chewable Tablet (Grape) (37205-0055) (Leader Brand Products) (off market)

Mapap Children's 80mg Chewable Tablet (00904-1974) (Major Pharmaceuticals Inc) (off market)

Mapap Children's 80mg Chewable Tablet (00904-5256) (Major Pharmaceuticals Inc)

Pain & Fever 80mg Chewable Tablet (00536-1014) (Rugby Laboratories a Division of The Harvard Drug Group, LLC)

PediaCare Children's Smooth Melts Fever Reducer/Pain Reliever 160mg Chewable Tablet (Cherry) (Medtech Products, Inc a Prestige Brands Company)

Premier Value Children's Non-Aspirin 80mg Chewable Tablet (Fruit) (Chain Drug Consortium, LLC)

Select Brand Children's Pain Reliever 80mg Chewable Tablet (15127-0830) (Select Brand)

Tylenol Children's 80mg Chewable Tablet (50580-0486) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Tylenol Children's 80mg Chewable Tablet (Bubblegum) (50580-0430) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Tylenol Children's 80mg Soft Chew (Fruit Burst) (50580-0102) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Tylenol Children's 80mg Soft Chew (Grape) (50580-0104) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Acetaminophen Elixir

Apra 160mg/5ml Elixir (59390-0002) (Altaire Pharmaceuticals Inc)

Apra 160mg/5ml Elixir (59390-0074) (Altaire Pharmaceuticals Inc)

Mapap 160mg/5ml Elixir (Cherry) (00904-1985) (Major Pharmaceuticals Inc)

Acetaminophen Oral capsule

Aceta 500mg Capsule (00436-0958) (Century Pharmaceuticals Inc) (off market)

Acetaminophen 500mg Capsule (17236-0601) (Dixon Shane Inc) (off market)

Acetaminophen 500mg Capsule (52735-0723) (Family Pharmacy)

Acetaminophen 500mg Capsule (00820-0191) (Logen Pharmaceuticals Inc.) (off market)

Acetaminophen 500mg Capsule (10135-0225) (Marlex Pharmaceuticals) (off market)

Acetaminophen 500mg Capsule (11845-0950) (Mason Vitamins)

Acetaminophen 500mg Capsule (60814-0148) (Rexall Group) (off market)

Acetaminophen 500mg Capsule (00536-3230) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)

Acetaminophen 500mg Capsule (00677-0678) (United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical Industries, Inc.) (off market)

Acetaminophen 500mg Capsule (11383-0012) (Weeks and Leo)

Mapap 500mg Capsule (00904-1987) (Major Pharmaceuticals Inc) (off market)

Mapap 500mg Gelcap (00904-1989) (Major Pharmaceuticals Inc) (off market)

Walgreens Acetaminophen 500mg Extra Strength Gelcap (00363-0325) (Walgreen Co)

XS No Aspirin Pain Reliever Capsule (00084-0050) (Natural Nutritionals Company) (off market)

Acetaminophen Oral disintegrating tablet

CVS Children's Pain Relief 80mg Rapid Tab (Bubblegum) (CVS Pharmacy, Inc)

CVS Children's Pain Relief 80mg Rapid Tab (Grape) (CVS Pharmacy, Inc)

CVS Junior Pain Relief 160mg Rapid Tab (Bubblegum) (CVS Pharmacy, Inc)

CVS Junior Pain Relief 160mg Rapid Tab (Grape) (CVS Pharmacy, Inc)

GNP Children's Easy-Melts 80mg Tablet (Bubblegum) (46122-0131) (AmerisourceBergen Corporation)

GNP Children's Easy-Melts 80mg Tablet (Grape) (46122-0133) (AmerisourceBergen Corporation)

Junior Mapap 160mg Rapid Orally Disintegrating Tablet (Bubble Gum) (00904-5754) (Major Pharmaceuticals Inc) (off market)

Junior Mapap 160mg Rapid Tab (Bubble Gum) (00904-5754) (Major Pharmaceuticals Inc)

Leader Children's Pain Reliever 80mg Rapid Melts Tablet (Bubblegum) (37205-0516) (Cardinal Health, Inc.)

Mapap Children's 80mg Rapid Orally Disintegrating Tablet (Bubble gum) (00904-5751) (Major Pharmaceuticals Inc)

Mapap Children's 80mg Rapid Orally Disintegrating Tablet (Grape) (00904-5791) (Major Pharmaceuticals Inc)

Premier Value Children's Non-Aspirin 80mg Quick Melt Tab (Grape) (68016-0019) (Chain Drug Consortium, LLC) (off market)

Premier Value Children's Pain Reliever 80mg Quick Melt Tablet (Grape) (68016-0196) (Chain Drug Consortium, LLC)

Premier Value Jr. Non-Aspirin 160mg Quick Melt (Grape) (68016-0019) (Chain Drug Consortium, LLC) (off market)

Premier Value Junior Pain Reliever 160mg Quick Melt Tablet (Grape) (68016-0198) (Chain Drug Consortium, LLC)

RITE AID Junior Acetaminophen 160mg Rapid Melts Tablet (Bubble Gum) (Rite Aid Corp)

RITE AID Junior Acetaminophen 160mg Rapid Melts Tablet (Grape) (Rite Aid Corp)

Sunmark Junior Pain Reliever Fever Reducer 160mg Rapid Melt (Bubblegum) (49348-0063) (McKesson Corporation)

Tylenol Children's 80mg Meltaways (Bubblegum Burst) (00045-0519) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Children's 80mg Meltaways (Grape Punch) (00045-0518) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Children's 80mg Meltaways (Wacky Watermelon) (50580-0516) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

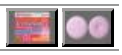
Tylenol Junior 160mg Meltaways (Bubblegum Burst) (50580-0513) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Junior 160mg Meltaways (Grape Punch) (00045-0514) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Walgreens Children's Acetaminophen 80mg Rapid Tab (Bubble Gum) (00363-0447) (Walgreen Co)

Walgreens Children's Acetaminophen 80mg Rapid Tab (Grape) (00363-0452) (Walgreen Co)

Walgreens Junior Acetaminophen 160mg Rapid Tab (Bubble Gum) (00363-0450) (Walgreen Co)



Walgreens Junior Acetaminophen 160mg Rapid Tab (Grape) (00363-0449) (Walgreen Co)

Walgreens Junior Pain & Fever 160mg Fast Dissolving Tablet (Bubblegum) (11917-0086) (Walgreen Co)

Acetaminophen Oral drops, solution

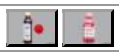
Infant Q-Pap 80mg/0.8ml Drops (Fruit) (00603-0838) (Qualitest Pharmaceuticals Inc)	
Infantaire 80mg/0.8ml Drops (59390-0001) (Altaire Pharmaceuticals Inc)	
Infants' Acetaminophen 80mg/0.8ml Drops (00182-6009) (Ivax Corporation a Division of Teva USA) (off market)	
Infants' Genapap 80mg/0.8ml Drops (00182-1477) (Ivax Corporation a Division of Teva USA) (off market)	
Infants' Mapap 80mg/0.8ml Drops (00904-5901) (Major Pharmaceuticals Inc) (off market)	
Infants' Mapap 80mg/0.8ml Drops (00904-6158) (Major Pharmaceuticals Inc) (off market)	
Infants' Silapap Drops (54838-0145) (Silarx Pharmaceuticals Inc) (off market)	
Mapap 80mg/0.8ml Drops (00904-5255) (Major Pharmaceuticals Inc) (off market)	
Nortemp 80mg/0.8ml Drops (Cherry) (63162-0518) (Ballay Pharmaceuticals)	
Pain and Fever 80mg/0.8ml Drops (00536-1936) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)	
Pediaphen 80mg/0.8ml Concentrated Drops (Cherry) (42192-0504) (BrookstonePharma, inc) (off market)	
Top Care Infants' Pain Relief 80mg/0.8ml Drops (Cherry) (36800-0008) (Topco Associates LLC)	
Tylenol Infants' 80mg/0.8ml Concentrated Drops (Cherry) (00045-0167) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)	
Tylenol Infants' 80mg/0.8ml Concentrated Drops (Cherry) (00045-0186) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)	
Tylenol Infants' 80mg/0.8ml Concentrated Drops (Grape) (50580-0122) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)	
Tylenol Infants' 80mg/0.8ml Concentrated Drops (grape) (00045-0122) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)	

Acetaminophen Oral drops, suspension

Equaline Infants' Pain Relief 80mg/0.8ml Drops (41163-0008) (Albertson's, Inc)	
Equaline Infants' Pain Relief Drops (grape) (41163-0289) (Albertson's, Inc)	
GNP Infants' Pain Relief 80mg/0.8ml Concentrated Drops (Cherry) (24385-0313) (AmerisourceBergen Corporation)	
GoodSense Infants' Pain Relief 80mg/0.8ml Concentrated Drops (Cherry) (00113-0008) (Goodsense a Division of Perrigo) (off market)	
GoodSense Infants' Pain Relief 80mg/0.8ml Concentrated Drops (Grape) (00113-0289) (Goodsense a Division of Perrigo) (off market)	
Leader Infants' Pain Reliever Concentrated Suspension Drops (37205-0008) (Leader Brand Products) (off market)	
Publix Infants' Pain Relief 80mg/0.8ml Concentrated Drops (Cherry) (56062-0008) (Publix Super Markets, Inc)	
RITE AID Infants' Pain Relief 80mg/0.8ml Concentrated Drops (Cherry) (Rite Aid Corp)	
Top Care Infants' Pain Relief 80mg/0.8ml Concentrated Drops (Grape) (Topco Associates LLC)	
Top Care Infants' Pain Relief 80mg/0.8ml Concentrated Drops (Grape) (Topco Associates LLC)	
Walgreens Infants' Non-Aspirin 80mg/0.8ml Drops (Cherry) (00363-0008) (Walgreen Co)	
Walgreens Infants' Non-Aspirin 80mg/0.8ml Drops (Grape) (00363-0289) (Walgreen Co)	 

Acetaminophen Oral solution

Acetaminophen 120mg/5ml Solution (00121-0259) (Pharmaceutical Associates Inc Div Beach Products) (off market)	
Acetaminophen 160mg/5ml Liquid (58657-0520) (Method Pharmaceuticals)	
Acetaminophen 160mg/5ml Solution (00472-0647) (Actavis Inc.) (off market)	
Acetaminophen 160mg/5ml Solution (00472-1410) (Actavis Inc.) (off market)	
Acetaminophen 160mg/5ml Solution (00364-0731) (Actavis Inc. formerly Watson Pharmaceuticals Inc) (off market)	
Acetaminophen 160mg/5ml Solution (50383-0099) (Hi-Tech Pharmacal Company Inc) (off market)	

Acetaminophen 160mg/5ml Solution (00182-1473) (Ivax Corporation a Division of Teva USA) (off market)	
Acetaminophen 160mg/5ml Solution (00182-6177) (Ivax Corporation a Division of Teva USA) (off market)	
Acetaminophen 160mg/5ml Solution (00426-8610) (Morton Grove Pharmaceuticals Inc) (off market)	
Acetaminophen 160mg/5ml Solution (60432-0081) (Morton Grove Pharmaceuticals Inc) (off market)	
Acetaminophen 160mg/5ml Solution (60432-0120) (Morton Grove Pharmaceuticals Inc) (off market)	
Acetaminophen 160mg/5ml Solution (60432-0610) (Morton Grove Pharmaceuticals Inc) (off market)	
Acetaminophen 160mg/5ml Solution (00121-0657) (Pharmaceutical Associates Inc Div Beach Products)	
Acetaminophen 160mg/5ml Solution (00536-0124) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)	
Acetaminophen 160mg/5ml Solution (00781-6377) (Sandoz Inc) (off market)	
Acetaminophen 160mg/5ml Solution (00677-1839) (United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical Industries, Inc.) (off market)	
Acetaminophen 500mg/5ml Solution (00121-0538) (Pharmaceutical Associates Inc Div Beach Products) (off market)	
Acetaminophen 80mg/0.8ml Drops (00472-1417) (Actavis Inc.) (off market)	
Acetaminophen 80mg/0.8ml Drops (00364-0730) (Actavis Inc. formerly Watson Pharmaceuticals Inc) (off market)	
Acetaminophen 80mg/0.8ml Drops (57896-0882) (Geri-Care Pharmaceuticals)	
Acetaminophen 80mg/0.8ml Drops (57896-0883) (Geri-Care Pharmaceuticals)	
Acetaminophen 80mg/0.8ml Drops (50383-0095) (Hi-Tech Pharmacal Company Inc) (off market)	
Acetaminophen 80mg/0.8ml Drops (50383-0101) (Hi-Tech Pharmacal Company Inc) (off market)	
Acetaminophen 80mg/0.8ml Drops (00182-7029) (Ivax Corporation a Division of Teva USA) (off market)	
Acetaminophen 80mg/0.8ml Drops (00182-7030) (Ivax Corporation a Division of Teva USA) (off market)	
Acetaminophen 80mg/0.8ml Drops (00536-0123) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)	
Acetaminophen 80mg/0.8ml Drops (00536-0133) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)	
APAP 500 Adult 500mg/5ml Liquid (60258-0050) (Cypress Pharmaceutical Inc. a wholly-owned subsidiary of Pernix Therapeutics, LLC) (off market)	
Children's ED-APAP 80mg/2.5ml Solution (00485-0057) (Edwards Pharmaceuticals Inc, a Division of WomenGÇÖs Choice Pharmaceuticals)	
Children's Pain and Fever 160mg/5ml Solution (00536-0122) (Rugby Laboratories a Division of The Harvard Drug Group, LLC)	
Children's Pain and Fever 160mg/5ml Solution (00536-0122) (Rugby Laboratories a Division of The Harvard Drug Group, LLC)	
Children's Silapap 160mg/5ml Liquid (Cherry) (54838-0144) (Silarx Pharmaceuticals Inc)	
Children's Silapap 160mg/5ml Liquid (Grape) (54838-0118) (Silarx Pharmaceuticals Inc) (off market)	
Comtrex Maximum Strength Sore Throat Relief 500mg/15ml Solution (Bristol Myers Squibb Co)	
Comtrex Sore Throat 1000mg/30ml Liquid (Honey Lemon) (Bristol Myers Squibb Co)	
CVS Pain Relief 500mg/15mL Extra Strength Rapid Burst Liquid (Cherry) (59779-0166) (CVS Pharmacy, Inc)	
ElixSure Fever/Pain 160mg/5ml Solution (Bubblegum) (51672-2500) (TaroPharma) (off market)	
ElixSure Fever/Pain 160mg/5ml Solution (Cherry) (Alterna LLC)	
ElixSure Fever/Pain 160mg/5ml Solution (Cherry) (51672-2501) (TaroPharma) (off market)	
ElixSure Fever/Pain 160mg/5ml Solution (Grape) (51672-2502) (TaroPharma) (off market)	
Goody's Back & Body Pain Relief Liquid (Orange) (Medtech Products, Inc a Prestige Brands Company)	
Goody's Back & Body Pain Relief Liquid (Orange) (Medtech Products, Inc a Prestige Brands Company)	
Infants' Acetaminophen 80mg/0.8ml Drops (00472-1417) (Actavis Inc.) (off market)	

LIQUID PAIN RELIEF 160mg/5ml Solution (Cherry) (57896-0180) (Geri-Care Pharmaceuticals)

Mapap 500mg/15ml Extra Strength Rapid Burst Liquid (Cherry) (00904-5847) (Major Pharmaceuticals Inc) (off market)

Mapap 500mg/15ml Extra Strength Rapid Burst Liquid (Cherry) (00904-5847) (Major Pharmaceuticals Inc)

Premier Value Rapid Burst Acetaminophen Extra Strength 500mg/15ml Liquid (Cherry) (68016-0166) (Chain Drug Consortium, LLC)

Q-Pap 160mg/5ml Liquid (Cherry) (00603-0839) (Qualitest Pharmaceuticals Inc) 

Q-Pap 160mg/5ml Liquid (Grape) (00603-0840) (Qualitest Pharmaceuticals Inc)

Triaminic Fever Reducer and Pain Reliever Solution (Bubble gum) (00067-6432) (GlaxoSmithKline Consumer Healthcare formerly Novartis Consumer Health)

Triaminic Fever Reducer and Pain Reliever Solution (Grape) (00067-6431) (GlaxoSmithKline Consumer Healthcare formerly Novartis Consumer Health)

Triaminic Infants' Fever Reducer and Pain Reliever Solution (Bubble gum) (00067-6441) (GlaxoSmithKline Consumer Healthcare formerly Novartis Consumer Health) 

Triaminic Infants' Fever Reducer and Pain Reliever Solution (Grape) (00067-6440) (GlaxoSmithKline Consumer Healthcare formerly Novartis Consumer Health) 

Tylenol Extra Strength 500mg/15ml Liquid (cherry) (00045-0500) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Sore Throat 1000mg/30ml Liquid (cherry) (50580-0913) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Tylenol Sore Throat 1000mg/30ml Liquid (honey lemon) (50580-0914) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Tylenol Sore Throat Daytime 1000mg/30ml Cool Burst Liquid (00045-0813) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Walgreens Pain Reliever 500mg/15mL Extra Strength Liquid (11917-0157) (Walgreen Co)

Acetaminophen Oral suspension

Acetaminophen 160mg/5ml Suspension (00121-4781) (Pharmaceutical Associates Inc Div Beach Products) (off market)

Apra 160mg/5ml Suspension (59390-0040) (Altaire Pharmaceuticals Inc) (off market)

Children's Acetaminophen 160mg/5ml Suspension (00121-1781) (Pharmaceutical Associates Inc Div Beach Products)

Children's Acetaminophen 160mg/5ml Suspension (Cherry) (45802-0203) (Perrigo Pharmaceuticals Company)

Children's Acetaminophen 160mg/5ml Suspension (Grape) (45802-0201) (Perrigo Pharmaceuticals Company)

Children's Acetaminophen 160mg/5ml Suspension (Grape) (68094-0593) (Precision Dose, Inc.) (off market)

Children's Acetaminophen 160mg/5ml Suspension (Grape) (68094-0594) (Precision Dose, Inc.)

Children's Acetaminophen 160mg/5ml Suspension (Grape) (68094-0605) (Precision Dose, Inc.)

Children's Acetaminophen 160mg/5ml Suspension (Grape) (68094-0587) (Precision Dose, Inc.)

Children's Acetaminophen 325mg/10.15ml Suspension (Grape) (68094-0614) (Precision Dose, Inc.) (off market)

Children's Acetaminophen 325mg/10.15ml Suspension (Grape) (68094-0588) (Precision Dose, Inc.)

Children's Acetaminophen 650mg/20.3ml Suspension (Grape) (68094-0650) (Precision Dose, Inc.) (off market)

Children's Acetaminophen 80mg/2.5mL Suspension (Grape) (68094-0583) (Precision Dose, Inc.) (off market)

Children's Acetaminophen 80mg/2.5mL Suspension (Grape) (68094-0586) (Precision Dose, Inc.)

Children's Pain and Fever 160mg/5ml Suspension (Cherry) (00536-3606) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) 

Children's Q-Pap 160mg/5ml Suspension (Bubble Gum) (00603-0841) (Qualitest Pharmaceuticals Inc)

Children's Q-Pap 160mg/5ml Suspension (Cherry) (00603-0842) (Qualitest Pharmaceuticals Inc)

Children's Q-Pap 160mg/5ml Suspension (Grape) (00603-0843) (Qualitest Pharmaceuticals Inc)

CVS Children's Pain & Fever 160mg/5ml Suspension (Strawberry) (CVS Pharmacy, Inc)

CVS Children's Pain Relief 160mg/5ml Suspension (Bubble Gum) (59779-0105) (CVS Pharmacy, Inc)

CVS Children's Pain Relief 160mg/5ml Suspension (Cherry) (59779-0175) (CVS Pharmacy, Inc) 

CVS Children's Pain Relief 160mg/5ml Suspension (Cherry) (CVS Pharmacy, Inc) 

CVS Children's Pain Relief 160mg/5ml Suspension (Grape) (59779-0130) (CVS Pharmacy, Inc) 

CVS Children's Pain Relief 160mg/5ml Suspension (Grape) (CVS Pharmacy, Inc)

CVS Children's Pain Relief 160mg/5mL Suspension (Tropical Punch) (59779-0104) (CVS Pharmacy, Inc)

CVS Infants' Pain & Fever 160mg/5ml Suspension (Cherry) (59779-0590) (CVS Pharmacy, Inc) 

CVS Infants' Pain and Fever 160mg/5ml Suspension (Cherry) (59779-0161) (CVS Pharmacy, Inc) 

CVS Infants' Pain and Fever 160mg/5ml Suspension (Cherry) (59779-0161) (CVS Pharmacy, Inc)

CVS Infants' Pain and Fever 160mg/5ml Suspension (Cherry) (59779-0161) (CVS Pharmacy, Inc) 

CVS Infants' Pain and Fever 160mg/5ml Suspension (Grape) (59779-0946) (CVS Pharmacy, Inc) 

CVS Infants' Pain Relief 160mg/5mL Suspension (Bubble Gum) (59779-0178) (CVS Pharmacy, Inc)

Equaline Children's Pain Relief Suspension (Bubble Gum) (41163-0105) (Albertson's, Inc)

Equaline Children's Pain Relief Suspension (Cherry) (41163-0175) (Albertson's, Inc)

GNP Children's Pain and Fever 160mg/5ml Suspension (Cherry) (46122-0105) (AmerisourceBergen Corporation)

GNP Children's Pain Relief 160mg/5ml Suspension (Bubble Gum) (24385-0105) (AmerisourceBergen Corporation)

GNP Children's Pain Relief 160mg/5ml Suspension (Cherry) (46122-0019) (AmerisourceBergen Corporation)

GNP Children's Pain Relief 160mg/5ml Suspension (Cherry) (24385-0146) (AmerisourceBergen Corporation)

GNP Children's Pain Relief 160mg/5ml Suspension (Grape) (24385-0130) (AmerisourceBergen Corporation)

GNP Children's Pain Relief 160mg/5ml Suspension (Grape) (46122-0106) (AmerisourceBergen Corporation)

GNP Infants' Pain and Fever 160mg/5ml Suspension (46122-0056) (AmerisourceBergen Corporation)

GNP Infants' Pain and Fever 160mg/5ml Suspension (Grape) (46122-0042) (AmerisourceBergen Corporation)

GNP Infants' Pain Relief 160mg/5ml Suspension (Cherry) (46122-0050) (AmerisourceBergen Corporation)

GNP Infants' Pain Relief 160mg/5ml Suspension (Grape) (46122-0042) (AmerisourceBergen Corporation)

GoodSense Children's Pain & Fever 160mg/5mL Suspension (Cherry) (00113-0608) (Goodsense a Division of Perrigo)

GoodSense Children's Pain Relief 160mg/5ml Suspension (Bubblegum) (00113-0105) (Goodsense a Division of Perrigo)

GoodSense Children's Pain Relief 160mg/5ml Suspension (Cherry) (00113-0175) (Goodsense a Division of Perrigo) (off market)

GoodSense Children's Pain Relief 160mg/5ml Suspension (Grape) (00113-0130) (Goodsense a Division of Perrigo) (off market)

GoodSense Children's Pain Relief 160mg/5ml Suspension (Grape) (00113-0212) (Goodsense a Division of Perrigo)

Health Mart Children's Pain and Fever 160mg/5ml Suspension (Cherry) (62011-0022) (McKesson Corporation)

Health Mart Children's Pain and Fever 160mg/5ml Suspension (Cherry) (62011-0247) (McKesson Corporation)

Health Mart Children's Pain and Fever 160mg/5ml Suspension (Grape) (62011-0029) (McKesson Corporation)

Health Mart Children's Pain and Fever 160mg/5ml Suspension (Grape) (62011-0183) (McKesson Corporation)

Health Mart Infants' Pain and Fever 160mg/5ml Suspension (Cherry) (62011-0002) (McKesson Corporation)

Health Mart Infants' Pain and Fever 160mg/5ml Suspension (Grape) (62011-0001) (McKesson Corporation)

Infants' Acetaminophen 200mg/2ml Concentrated Suspension (68094-0703) (Precision Dose, Inc.) (off market) 

Infants' Acetaminophen 80mg/0.8ml Concentrated Suspension (68094-0692) (Precision Dose, Inc.) (off market)

Infants' Mapap 160mg/5ml Suspension (Cherry) (00904-6244) (Major Pharmaceuticals Inc) (off market) 

Infants' Mapap 160mg/5ml Suspension (Cherry) (00904-6307) (Major Pharmaceuticals Inc) (off market)

Leader Children's Pain & Fever 160mg/5ml Suspension (Cherry) (37205-0676) (Cardinal Health, Inc.)

Leader Children's Pain & Fever 160mg/5ml Suspension (Strawberry) (49781-0010) (Cardinal Health, Inc.)

Leader Children's Pain Reliever 160mg/5ml Suspension (Bubblegum) (37205-0717) (Cardinal Health, Inc.) 

Leader Children's Pain Reliever 160mg/5ml Suspension (Strawberry) (37205-0627) (Cardinal Health, Inc.)

Leader Children's Pain Reliever Suspension (cherry) (37205-0508) (Cardinal Health, Inc.)

Leader Children's Pain Reliever Suspension (grape) (37205-0518) (Cardinal Health, Inc.)

Leader Infants' Pain & Fever 160mg/5ml Suspension (Cherry) (37205-0575) (Cardinal Health, Inc.)

Leader Infants' Pain & Fever 160mg/5ml Suspension (Cherry) (37205-0577) (Cardinal Health, Inc.)

Leader Infants' Pain & Fever 160mg/5ml Suspension (Grape) (37205-0576) (Cardinal Health, Inc.)

Little Fevers Children's 160mg/5ml Suspension (Cherry) (Prestige Brands Inc)

Little Fevers Children's Fever/Pain Reliever 160mg/5ml Suspension (Grape) (Prestige Brands Inc)

Little Fevers Infants' 160mg/5ml Suspension (Berry) (Prestige Brands Inc)

Little Fevers Infants' 160mg/5ml Suspension (Grape) (Prestige Brands Inc)

Mapap Children's 160mg/5ml Suspension (Cherry) (00904-5116) (Major Pharmaceuticals Inc) (off market)

Mapap Children's 160mg/5ml Suspension (Cherry) (00904-6308) (Major Pharmaceuticals Inc)

Nortemp Children's 160mg/5ml Oral Suspension (Cotton Candy) (63162-0510) (Ballay Pharmaceuticals)

PediaCare Children's Fever Reducer/Pain Reliever 160mg/5ml Suspension (Bubble Gum) (Medtech Products, Inc a Prestige Brands Company)

PediaCare Children's Fever Reducer/Pain Reliever 160mg/5ml Suspension (Cherry) (Medtech Products, Inc a Prestige Brands Company)

PediaCare Children's Fever Reducer/Pain Reliever 160mg/5ml Suspension (Cherry) (Medtech Products, Inc a Prestige Brands Company)

PediaCare Children's Fever Reducer/Pain Reliever 160mg/5ml Suspension (Grape) (Medtech Products, Inc a Prestige Brands Company)

PediaCare Infants' Fever Reducer/Pain Reliever 160mg/5ml Suspension (Bubble Gum) (Medtech Products, Inc a Prestige Brands Company)

PediaCare Infants' Fever Reducer/Pain Reliever 160mg/5ml Suspension (Cherry) (Medtech Products, Inc a Prestige Brands Company)

PediaCare Infants' Fever Reducer/Pain Reliever 160mg/5ml Suspension (Cherry) (Medtech Products, Inc a Prestige Brands Company)

PediaCare Infants' Fever Reducer/Pain Reliever 160mg/5ml Suspension (Grape) (Medtech Products, Inc a Prestige Brands Company)

Premier Value Children's Non-Aspirin Pain Relief 160mg/5ml Suspension (Bubble Gum) (68016-0178) (Chain Drug Consortium, LLC)

Premier Value Children's Non-Aspirin Pain Relief 160mg/5ml Suspension (Cherry) (68016-0103) (Chain Drug Consortium, LLC)

Premier Value Children's Pain Relief 160mg/5ml Suspension (Cherry) (68016-0103) (Chain Drug Consortium, LLC) (off market)

Premier Value Children's Pain Relief 160mg/5ml Suspension (Cherry) (68016-0725) (Chain Drug Consortium, LLC)

Premier Value Children's Pain Relief 160mg/5ml Suspension (Grape) (68016-0699) (Chain Drug Consortium, LLC)

Premier Value Infants' Pain Relief 160mg/5ml Suspension (Bubble Gum) (68016-0178) (Chain Drug Consortium, LLC)

Premier Value Infants' Pain Relief 160mg/5ml Suspension (Bubble Gum) (68016-0702) (Chain Drug Consortium, LLC)

Premier Value Infants' Pain Relief 160mg/5ml Suspension (Cherry) (68016-0160) (Chain Drug Consortium, LLC)

Premier Value Infants' Pain Relief 160mg/5ml Suspension (Cherry) (68016-0703) (Chain Drug Consortium, LLC)

Premier Value Infants' Pain Relief 160mg/5ml Suspension (Grape) (68016-0141) (Chain Drug Consortium, LLC)

Premier Value Infants' Pain Relief 160mg/5ml Suspension (Grape) (68016-0704) (Chain Drug Consortium, LLC)

Publix Children's Pain Relief 160mg/5ml Suspension (Cherry) (56062-0175) (Publix Super Markets, Inc)

RITE AID Children's Fever Reducer/Pain Reliever 160mg/5ml Suspension (Bubblegum) (Rite Aid Corp)

RITE AID Children's Fever Reducer/Pain Reliever 160mg/5ml Suspension (Cherry) (Rite Aid Corp)

RITE AID Children's Fever Reducer/Pain Reliever 160mg/5ml Suspension (Grape) (Rite Aid Corp)

RITE AID Infants' Fever Reducer & Pain Reliever 160mg/5ml Suspension (Cherry) (Rite Aid Corp)

RITE AID Infants' Fever Reducer & Pain Reliever 160mg/5ml Suspension (Cherry) (Rite Aid Corp)

RITE AID Infants' Fever Reducer & Pain Reliever 160mg/5ml Suspension (Grape) (Rite Aid Corp)

Select Brand Children's Pain Reliever Suspension (Bubble Gum) (15127-0510) (Select Brand)

Select Brand Children's Pain Reliever Suspension (Grape) (15127-0509) (Select Brand) 

Sunmark Children's Pain & Fever 160mg/5ml Suspension (Cherry) (49348-0123) (McKesson Corporation)

Sunmark Children's Pain & Fever 160mg/5ml Suspension (Grape) (49348-0325) (McKesson Corporation)

Sunmark Children's Pain & Fever 160mg/5ml Suspension (Grape) (49348-0119) (McKesson Corporation)

Sunmark Children's Pain Reliever Suspension (Bubble Gum) (49348-0888) (McKesson Corporation)

Sunmark Children's Pain Reliever Suspension (Cherry) (49348-0797) (McKesson Corporation)

Sunmark Children's Pain Reliever Suspension (Grape) (49348-0266) (McKesson Corporation)

Sunmark Infants' Pain & Fever 160mg/5ml Suspension (Cherry) (49348-0081) (McKesson Corporation)

Sunmark Infants' Pain Relief 160mg/5ml Suspension (Grape) (49348-0309) (McKesson Corporation)

Sunmark Infants' Pain Relief 160mg/5ml Suspension (Grape) (49348-0430) (McKesson Corporation)

Today's Health Children's Pain Reliever Suspension (Bubble Gum) (Todays Health, Inc)

Today's Health Children's Pain Reliever Suspension (Cherry) (Todays Health, Inc)

Today's Health Children's Pain Reliever Suspension (Grape) (Todays Health, Inc)

Top Care Children's Pain Relief 160mg/5ml Suspension (Bubblegum) (36800-0105) (Topco Associates LLC)

Top Care Children's Pain Relief 160mg/5ml Suspension (Cherry) (36800-0175) (Topco Associates LLC)

Top Care Children's Pain Relief 160mg/5ml Suspension (Grape) (36800-0130) (Topco Associates LLC)

Top Care Children's Pain Relief 160mg/5ml Suspension (Strawberry) (Topco Associates LLC)

Top Care Infants' Pain and Fever 160mg/5mL Suspension (Cherry) (Topco Associates LLC)

Top Care Infants' Pain and Fever 160mg/5mL Suspension (Grape) (Topco Associates LLC)

Tylenol Children's 160mg/5ml Suspension (Bubblegum) (00045-0407) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Children's 160mg/5ml Suspension (Cherry Blast) (00045-0123) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Children's 160mg/5ml Suspension (Cherry) (00045-0166) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Children's 160mg/5ml Suspension (Grape Splash) (00045-0296) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Children's 160mg/5ml Suspension (Very Berry Strawberry) (00045-0493) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Children's160mg/5ml Suspension with Flavor Creators (50580-0454) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Infants' 160mg/5mL Suspension (Cherry) (00045-0186) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Infants' 160mg/5mL Suspension (Grape) (00045-0122) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Walgreens Children's Dye-Free Pain & Fever 160mg/5ml Suspension (Cherry) (11917-0120) (Walgreen Co)

Walgreens Children's Non-Aspirin 160mg/5ml Suspension (Bubble Gum) (00363-0105) (Walgreen Co) 

Walgreens Children's Non-Aspirin 160mg/5ml Suspension (Cherry) (00363-0175) (Walgreen Co) 

Walgreens Children's Non-Aspirin 160mg/5ml Suspension (Grape) (00363-0130) (Walgreen Co) 

Walgreens Children's Pain & Fever 160mg/5mL Suspension (Bubble Gum) (11917-0113) (Walgreen Co)

Walgreens Infants' Dye-Free Pain & Fever 160mg/5mL Suspension (Cherry) (11917-0165) (Walgreen Co)

Walgreens Infants' Dye-Free Pain & Fever 160mg/5mL Suspension (Grape) (11917-0165) (Walgreen Co)

Walgreens Infants' Pain & Fever 160mg/5mL Suspension (Cherry) (11917-0165) (Walgreen Co)

Walgreens Infants' Pain & Fever 160mg/5mL Suspension (Cherry) (11917-0132) (Walgreen Co)

Walgreens Infants' Pain & Fever 160mg/5mL Suspension (Grape) (11917-0165) (Walgreen Co)

Walgreens Infants' Pain & Fever 160mg/5mL Suspension (Grape) (11917-0132) (Walgreen Co)

Acetaminophen Oral tablet

Aceta 325mg Tablet (00436-0410) (Century Pharmaceuticals Inc) (off market)

Acetaminophen 325mg Tablet (52152-0030) (Actavis Inc. formerly Amide Pharmaceutical Inc) (off market)

Acetaminophen 325mg Tablet (00228-1103) (Actavis Inc. formerly Purepac Pharmaceutical Co) (off market)

Acetaminophen 325mg Tablet (00364-0022) (Actavis Inc. formerly Watson Pharmaceuticals Inc) (off market)

Acetaminophen 325mg Tablet (65162-0350) (Akyma Pharmaceuticals) (off market)

Acetaminophen 325mg Tablet (65162-0350) (Amneal Pharmaceuticals LLC) (off market)

Acetaminophen 325mg Tablet (20254-0200) (Concord Laboratories Inc) (off market)

Acetaminophen 325mg Tablet (58865-0005) (Dawn Pharmaceutical)

Acetaminophen 325mg Tablet (17236-0350) (Dixon Shane Inc) (off market)

Acetaminophen 325mg Tablet (52735-0709) (Family Pharmacy)

Acetaminophen 325mg Tablet (52569-0851) (Generamed Inc)

Acetaminophen 325mg Tablet (57896-0100) (Geri-Care Pharmaceuticals)

Acetaminophen 325mg Tablet (57896-0881) (Geri-Care Pharmaceuticals)

Acetaminophen 325mg Tablet (60809-0100) (Glasgow Pharmaceutical Corporation)

Acetaminophen 325mg Tablet (53746-0011) (Interpharm Inc) (off market)

Acetaminophen 325mg Tablet (00182-8447) (Ivax Corporation a Division of Teva USA) (off market)

Acetaminophen 325mg Tablet (00182-1000) (Ivax Corporation a Division of Teva USA) (off market)

Acetaminophen 325mg Tablet (51111-0488) (J. B. Williams Co., Inc)

Acetaminophen 325mg Tablet (00820-0135) (Logen Pharmaceuticals Inc.) (off market)

Acetaminophen 325mg Tablet (10135-0163) (Marlex Pharmaceuticals)

Acetaminophen 325mg Tablet (10135-0123) (Marlex Pharmaceuticals)

Acetaminophen 325mg Tablet (49348-0009) (McKesson Drug Company)

Acetaminophen 325mg Tablet (63739-0002) (McKesson Packaging Inc) (off market)

Acetaminophen 325mg Tablet (63739-0440) (McKesson Packaging Inc)

Acetaminophen 325mg Tablet (47682-0145) (Medique Products)

Acetaminophen 325mg Tablet (47682-0803) (Medique Products)

Acetaminophen 325mg Tablet (57480-0100) (Medirex Inc) (off market)

Acetaminophen 325mg Tablet (51079-0002) (Mylan Institutional LLC formerly UDL Laboratories Inc) (off market) 

Acetaminophen 325mg Tablet (00084-0047) (Natural Nutritionals Company) (off market)

Acetaminophen 325mg Tablet (66267-0003) (NuCare Pharmaceuticals Inc) (off market)

Acetaminophen 325mg Tablet (66267-0999) (NuCare Pharmaceuticals Inc) (off market)

Acetaminophen 325mg Tablet	(00574-0007)	(Paddock Laboratories Inc, a Perrigo Family) (off market)
Acetaminophen 325mg Tablet	(55289-0563)	(PD-RX Pharmaceuticals)
Acetaminophen 325mg Tablet	(55289-0563)	(PD-RX Pharmaceuticals)
Acetaminophen 325mg Tablet	(55966-0000)	(PDK Labs Inc)
Acetaminophen 325mg Tablet	(69618-0010)	(Reliable 1 Laboratories LLC)
Acetaminophen 325mg Tablet	(00122-0825)	(Rexall Group) (off market)
Acetaminophen 325mg Tablet	(00122-0882)	(Rexall Group) (off market)
Acetaminophen 325mg Tablet	(60814-0142)	(Rexall Group) (off market)
Acetaminophen 325mg Tablet	(60814-0143)	(Rexall Group) (off market)
Acetaminophen 325mg Tablet	(00781-1294)	(Sandoz Inc) (off market)
Acetaminophen 325mg Tablet	(00093-0855)	(Teva Pharmaceuticals USA Inc) (off market)
Acetaminophen 325mg Tablet	(00093-0893)	(Teva Pharmaceuticals USA Inc) (off market)
Acetaminophen 325mg Tablet	(00677-1781)	(United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical Industries, Inc.) (off market) 
Acetaminophen 325mg Tablet	(00677-1974)	(United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical Industries, Inc.)
Acetaminophen 325mg Tablet	(11383-0139)	(Weeks and Leo)
Acetaminophen 500mg Caplet	(53746-0018)	(Interpharm Inc) (off market)
Acetaminophen 500mg Caplet	(63739-0439)	(McKesson Packaging Inc) (off market)
Acetaminophen 500mg Caplet	(43063-0224)	(PD-Rx Pharmaceuticals Incorporated)
Acetaminophen 500mg Caplet	(45802-0484)	(Perrigo Pharmaceuticals Company)
Acetaminophen 500mg Caplet	(00677-1975)	(United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical Industries, Inc.) (off market)
Acetaminophen 500mg Tablet	(52152-0044)	(Actavis Inc. formerly Amide Pharmaceutical Inc) (off market)
Acetaminophen 500mg Tablet	(00364-0553)	(Actavis Inc. formerly Watson Pharmaceuticals Inc) (off market)
Acetaminophen 500mg Tablet	(00364-0837)	(Actavis Inc. formerly Watson Pharmaceuticals Inc) (off market)
Acetaminophen 500mg Tablet	(65162-0607)	(Akyma Pharmaceuticals) (off market)
Acetaminophen 500mg Tablet	(65162-0602)	(Akyma Pharmaceuticals) (off market)
Acetaminophen 500mg Tablet	(65162-0607)	(Amneal Pharmaceuticals LLC) (off market)
Acetaminophen 500mg Tablet	(65162-0602)	(Amneal Pharmaceuticals LLC) (off market)
Acetaminophen 500mg Tablet	(20254-0201)	(Concord Laboratories Inc) (off market)
Acetaminophen 500mg Tablet	(20254-0202)	(Concord Laboratories Inc) (off market)
Acetaminophen 500mg Tablet	(20254-0203)	(Concord Laboratories Inc) (off market)
Acetaminophen 500mg Tablet	(58865-0006)	(Dawn Pharmaceutical)
Acetaminophen 500mg Tablet	(17236-0602)	(Dixon Shane Inc) (off market)
Acetaminophen 500mg Tablet	(17236-0607)	(Dixon Shane Inc) (off market)
Acetaminophen 500mg Tablet	(52735-0710)	(Family Pharmacy)
Acetaminophen 500mg Tablet	(52735-0712)	(Family Pharmacy)
Acetaminophen 500mg Tablet	(52569-0854)	(Generamed Inc)
Acetaminophen 500mg Tablet	(57896-0200)	(Geri-Care Pharmaceuticals)
Acetaminophen 500mg Tablet	(60809-0101)	(Glasgow Pharmaceutical Corporation)
Acetaminophen 500mg Tablet	(25077-2140)	(Hudson Corporation)

Acetaminophen 500mg Tablet	(25077-2141)	(Hudson Corporation)	
Acetaminophen 500mg Tablet	(25077-4490)	(Hudson Corporation)	
Acetaminophen 500mg Tablet	(25077-6800)	(Hudson Corporation)	
Acetaminophen 500mg Tablet	(53746-0001)	(Interpharm Inc) (off market)	
Acetaminophen 500mg Tablet	(00182-8453)	(Ivax Corporation a Division of Teva USA)	
Acetaminophen 500mg Tablet	(51111-0489)	(J. B. Williams Co., Inc)	
Acetaminophen 500mg Tablet	(00820-0136)	(Logen Pharmaceuticals Inc.) (off market)	
Acetaminophen 500mg Tablet	(00820-0138)	(Logen Pharmaceuticals Inc.) (off market)	
Acetaminophen 500mg Tablet	(10135-0164)	(Marlex Pharmaceuticals)	
Acetaminophen 500mg Tablet	(10135-0144)	(Marlex Pharmaceuticals)	
Acetaminophen 500mg Tablet	(10135-0152)	(Marlex Pharmaceuticals)	
Acetaminophen 500mg Tablet	(11845-0907)	(Mason Vitamins)	
Acetaminophen 500mg Tablet	(49348-0023)	(McKesson Drug Company)	
Acetaminophen 500mg Tablet	(49348-0042)	(McKesson Drug Company)	
Acetaminophen 500mg Tablet	(49348-0286)	(McKesson Drug Company)	
Acetaminophen 500mg Tablet	(49348-0871)	(McKesson Drug Company)	
Acetaminophen 500mg Tablet	(63739-0001)	(McKesson Packaging Inc) (off market)	
Acetaminophen 500mg Tablet	(47682-0804)	(Medique Products)	
Acetaminophen 500mg Tablet	(47682-0864)	(Medique Products)	
Acetaminophen 500mg Tablet	(57480-0102)	(Medirex Inc) (off market)	
Acetaminophen 500mg Tablet	(51079-0396)	(Mylan Institutional LLC formerly UDL Laboratories Inc) (off market)	
Acetaminophen 500mg Tablet	(00084-0049)	(Natural Nutritionals Company) (off market)	
Acetaminophen 500mg Tablet	(66267-0005)	(NuCare Pharmaceuticals Inc) (off market)	
Acetaminophen 500mg Tablet	(66267-0998)	(NuCare Pharmaceuticals Inc) (off market)	
Acetaminophen 500mg Tablet	(55289-0880)	(PD-RX Pharmaceuticals)	
Acetaminophen 500mg Tablet	(69618-0011)	(Reliable 1 Laboratories LLC)	
Acetaminophen 500mg Tablet	(00122-0805)	(Rexall Group) (off market)	
Acetaminophen 500mg Tablet	(00122-0806)	(Rexall Group) (off market)	
Acetaminophen 500mg Tablet	(00122-0845)	(Rexall Group) (off market)	
Acetaminophen 500mg Tablet	(00122-0863)	(Rexall Group) (off market)	
Acetaminophen 500mg Tablet	(00122-0883)	(Rexall Group) (off market)	
Acetaminophen 500mg Tablet	(60814-0147)	(Rexall Group) (off market)	
Acetaminophen 500mg Tablet	(60814-0149)	(Rexall Group) (off market)	
Acetaminophen 500mg Tablet	(00781-1834)	(Sandoz Inc) (off market)	
Acetaminophen 500mg Tablet	(00093-0856)	(Teva Pharmaceuticals USA Inc) (off market)	
Acetaminophen 500mg Tablet	(00093-0894)	(Teva Pharmaceuticals USA Inc) (off market)	
Acetaminophen 500mg Tablet	(00677-1782)	(United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical Industries, Inc.) (off market)	
Acetaminophen 500mg Tablet	(00677-1784)	(United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical Industries, Inc.) (off market)	
Acetaminophen 500mg Tablet	(00677-1976)	(United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical	

Industries, Inc.) (off market)

Acetaminophen 500mg Tablet (11383-0011) (Weeks and Leo)

Acetaminophen 500mg Tablet (11383-0138) (Weeks and Leo)

Acetaminophen 500mg Tablet (00143-1339) (West-Ward Pharmaceutical) (off market)

Acetaminophen 650mg Tablet (51079-0050) (Mylan Institutional LLC formerly UDL Laboratories Inc) (off market)

Actamin 325mg Tablet (10244-0565) (Otis Clapp and Son) (off market)

Actamin 500mg Tablet (10244-0575) (Otis Clapp and Son) (off market)

Actamin 500mg Tablet (10244-0584) (Otis Clapp and Son) (off market)

Anacin Aspirin Free 500mg Tablet (00573-0310) (Medtech Products, Inc a Prestige Brands Company formerly Insight Pharmaceuticals) (off market)

CVS Pain Relief Extra Strength 500mg Caplet (59779-0484) (CVS Pharmacy, Inc) 

CVS Pain Relief Extra Strength 500mg Caplet (59779-0975) (CVS Pharmacy, Inc) 

CVS Pain Relief Extra Strength 500mg Caplet (CVS Pharmacy, Inc)

CVS Pain Relief Extra Strength 500mg Caplet (CVS Pharmacy, Inc)

CVS Pain Relief Extra Strength 500mg Geltab (59779-0187) (CVS Pharmacy, Inc) 

CVS Pain Relief Extra Strength 500mg Rapid Release Gelcap (CVS Pharmacy, Inc) 

CVS Pain Relief Extra Strength 500mg Tablet (CVS Pharmacy, Inc) (off market) 

CVS Pain Relief Extra Strength 500mg Tablet (59779-0405) (CVS Pharmacy, Inc) 

CVS Pain Relief Extra Strength 500mg Tablet (CVS Pharmacy, Inc) 

CVS Pain Relief Extra Strength 500mg Tablet (CVS Pharmacy, Inc)

CVS Pain Relief Extra Strength 500mg Tablet (CVS Pharmacy, Inc)

CVS Pain Relief Extra Strength 500mg Tablet (CVS Pharmacy, Inc)

Equaline Extra Strength Pain Relief Caplet (41163-0484) (Albertson's, Inc)

Equaline Extra Strength Pain Relief Gelcap (41163-0976) (Albertson's, Inc)

Equaline Extra Strength Pain Relief Geltab (41163-0187) (Albertson's, Inc) 

Equaline Extra Strength Pain Relief Tablet (41163-0405) (Albertson's, Inc)

Equaline Regular Strength Pain Relief 325mg Tablet (41163-0403) (Albertson's, Inc)

Genapap 325mg Tablet (00182-1410) (Ivax Corporation a Division of Teva USA) (off market)

Genapap 500mg Caplet (00182-2152) (Ivax Corporation a Division of Teva USA) (off market)

Genapap 500mg Gelcap (00182-2154) (Ivax Corporation a Division of Teva USA) (off market)

Genapap 500mg Tablet (00182-1457) (Ivax Corporation a Division of Teva USA) (off market)

Genebs 325mg Tablet (00182-0141) (Ivax Corporation a Division of Teva USA) (off market) 

Genebs 500mg Caplet (00182-1832) (Ivax Corporation a Division of Teva USA) (off market)

Genebs 500mg Tablet (00182-1453) (Ivax Corporation a Division of Teva USA) (off market)

GNP Pain Relief 325mg Tablet (24385-0403) (AmerisourceBergen Corporation) 

GNP Pain Relief Extra Strength 500mg Caplet (24385-0484) (AmerisourceBergen Corporation) 

GNP Pain Relief Extra Strength 500mg Easy Tab Tablet (24385-0145) (AmerisourceBergen Corporation)

GNP Pain Relief Extra Strength 500mg Rapid Release Gelcap (46122-0003) (AmerisourceBergen Corporation)

GNP Pain Relief Extra Strength 500mg Tablet (24385-0405) (AmerisourceBergen Corporation) 

GNP Pain Relief Extra Strength 500mg Tablet (24385-0087) (AmerisourceBergen Corporation)

GoodSense Extra Strength Pain Relief 500mg Tablet (00113-0405) (Goodsense a Division of Perrigo) (off market)

GoodSense Pain Relief 325mg Tablet (00113-0403) (Goodsense a Division of Perrigo) (off market)

GoodSense Pain Relief 500mg Caplet (00113-0484) (Goodsense a Division of Perrigo) 

GoodSense Pain Relief Extra Strength 500mg Cool Ice Caplet (00113-0010) (Goodsense a Division of Perrigo) (off market)

GoodSense Pain Relief Extra Strength 500mg Tablet (00113-0227) (Goodsense a Division of Perrigo)

Health Mart Pain Relief Extra Strength 500mg Caplet (62011-0023) (McKesson Corporation) 

Health Mart Pain Relief Extra Strength 500mg Caplet (62011-0034) (McKesson Corporation)

Health Mart Pain Relief Extra Strength 500mg Easy To Swallow Tablet (62011-0027) (McKesson Corporation)

Health Mart Pain Reliever 325mg Tablet (62011-0032) (McKesson Corporation)

Leader Pain Reliever 500mg Gelcap (37205-0025) (Leader Brand Products) (off market) 

Leader Pain Reliever Extra Strength 500mg Caplet (37205-0594) (Cardinal Health, Inc.) 

Leader Pain Reliever Extra Strength 500mg Caplet (37205-0594) (Cardinal Health, Inc.) 

Leader Pain Reliever Extra Strength 500mg Caplet (37205-0594) (Cardinal Health, Inc.) 

Leader Pain Reliever Extra Strength 500mg Geltab (37205-0187) (Leader Brand Products) (off market)  

Leader Pain Reliever Extra Strength 500mg Rapid Release Gelcap (37205-0980) (Cardinal Health, Inc.)

Leader Pain Reliever Extra Strength 500mg Rapid Release Gelcap (37205-0980) (Cardinal Health, Inc.)

Leader Pain Reliever Extra Strength 500mg Tablet (37205-0593) (Cardinal Health, Inc.) 

Leader Pain Reliever Extra Strength 500mg Tablet (37205-0593) (Cardinal Health, Inc.) 

Leader Pain Reliever Extra Strength 500mg Tablet (37205-0659) (Cardinal Health, Inc.) 

Leader Pain Reliever Extra Strength 500mg Tablet (37205-0659) (Cardinal Health, Inc.) 

Leader Pain Reliever Extra Strength Caplet (37205-0020) (Leader Brand Products) (off market)

Leader Pain Reliever Extra Strength Tablet (37205-0035) (Leader Brand Products) (off market)

Leader Pain Reliever Tablet (37205-0031) (Leader Brand Products) (off market) 

Mapap 325mg Tablet (00904-1982) (Major Pharmaceuticals Inc) 

Mapap 325mg Tablet (00904-1982) (Major Pharmaceuticals Inc) (off market)

Mapap 500mg Caplet (00904-1983) (Major Pharmaceuticals Inc) 

Mapap 500mg Tablet (00904-1988) (Major Pharmaceuticals Inc) 

Mapap Extra Strength 500mg Rapid Release Gelcap (00904-5816) (Major Pharmaceuticals Inc)

Non-Aspirin Acetaminophen 500mg Tablet (59606-0020) (Leiner Health Products) (off market) 

Pain & Fever 325mg Tablet (00536-3222) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market) 

Pain & Fever 325mg Tablet (00536-3222) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) 

Pain and Fever 500mg Tablet (00536-3218) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) 

Pain and Fever 500mg Tablet (00536-3231) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market) 

Pain and Fever 500mg Tablet (00536-3231) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) 

Pain Relief 325mg Tablet (00761-0173) (Basic Vitamins) (off market)

PAIN RELIEF 325mg Tablet (57896-0101) (Geri-Care Pharmaceuticals)

Pain Relief 500mg Tablet (00761-0113) (Basic Vitamins) (off market)

Pain Relief 500mg Tablet (00761-0904) (Basic Vitamins) (off market)

PAIN RELIEF Extra-Strength 500mg Caplet (57896-0221) (Geri-Care Pharmaceuticals)

PAIN RELIEF Extra-Strength 500mg Tablet (57896-0201) (Geri-Care Pharmaceuticals)

Panadol 500mg Extra Strength Caplet (GlaxoSmithKline Consumer Healthcare) (off market)

PHARBETOL 500mg Tablet (16103-0376) (Pharbest Pharmaceuticals)

Premier Value Non-Aspirin 325mgTablet (68016-0012) (Chain Drug Consortium, LLC) (off market)

Premier Value Non-Aspirin 325mgTablet (68016-0246) (Chain Drug Consortium, LLC)

Premier Value Non-Aspirin Extra Strength 500mg Caplet (68016-0138) (Chain Drug Consortium, LLC)

Premier Value Non-Aspirin Extra Strength 500mg Tablet (68016-0139) (Chain Drug Consortium, LLC)

Premier Value Pain Relief Extra Strength 500mg Cool Caplet (68016-0027) (Chain Drug Consortium, LLC)

Premier Value Pain Relief Extra Strength 500mg Cool Caplet (68016-0027) (Chain Drug Consortium, LLC)

Premier Value Pain Relief Extra Strength 500mg Cool Caplet (68016-0027) (Chain Drug Consortium, LLC) (off market)

Premier Value Pain Relief Extra Strength 500mg Rapid Release Gelcap (68016-0029) (Chain Drug Consortium, LLC)

Premier Value Pain Relief Extra Strength 500mg Rapid Release Gelcap (68016-0029) (Chain Drug Consortium, LLC)

Premier Value Pain Relief Extra Strength 500mg Tablet (68016-0021) (Chain Drug Consortium, LLC)

Publix Pain Relief Extra Strength 500mg Caplet (56062-0484) (Publix Super Markets, Inc)

Publix Pain Relief Extra Strength 500mg Caplet (56062-0010) (Publix Super Markets, Inc)

Publix Pain Relief Extra Strength 500mg Tablet (56062-0227) (Publix Super Markets, Inc)

Publix Pain Relief Extra Strength Geltab (56062-0187) (Publix Super Markets, Inc)

Q-Pap 325mg Tablet (00603-0263) (Qualitest Pharmaceuticals Inc) 

Q-Pap Extra Strength 500mg Caplet (00603-0265) (Qualitest Pharmaceuticals Inc) (off market)

Q-Pap Extra Strength 500mg Tablet (00603-0268) (Qualitest Pharmaceuticals Inc) 

RITE AID Acetaminophen Extra Strength 500mg Easy Tab Tablet (Rite Aid Corp)

RITE AID Pain Relief 325mg Tablet (Rite Aid Corp) 

RITE AID Pain Relief Acetaminophen Extra Strength 500mg Caplet (Rite Aid Corp) 

RITE AID Pain Relief Acetaminophen Extra Strength 500mg Tablet (Rite Aid Corp) 

RITE AID Pain Relief Extra Strength 500mg Rapid Release Gelcap (Rite Aid Corp)

Select Brand Pain Reliever 325mg Tablet (15127-0072) (Select Brand) 

Select Brand Pain Reliever 500mg Caplet (15127-0735) (Select Brand) 

Select Brand Pain Reliever 500mg Rapid Release Gelcap (15127-0994) (Select Brand) 

Select Brand Pain Reliever 500mg Tablet (15127-0730) (Select Brand) 

Sunmark Pain Relief Extra Strength 500mg Rapid Release Gelcap (49348-0892) (McKesson Corporation)

Sunmark Pain Reliever 325mg Tablet (49348-0973) (McKesson Drug Company)

Sunmark Pain Reliever Extra Strength 500mg Rapid Release Gelcap (49348-0116) (McKesson Corporation)

Sunmark Pain Reliever Extra Strength 500mg Tablet (49348-0730) (McKesson Corporation)

Today's Health Acetaminophen Extra Strength 500mg Caplet (Todays Health, Inc)

Today's Health Acetaminophen Extra Strength 500mg Caplet (Todays Health, Inc)

Today's Health Acetaminophen Extra Strength 500mg Cool Taste Caplet (Todays Health, Inc)

Today's Health Acetaminophen Extra Strength 500mg Easy Tab Tablet (Todays Health, Inc)

Top Care Extra Strength Pain Relief 500mg Tablet (36800-0405) (Topco Associates LLC)

Top Care Pain Relief 325mg Tablet (36800-0403) (Topco Associates LLC)

Top Care Pain Relief 500mg Caplet (36800-0484) (Topco Associates LLC)

Top Care Pain Relief Extra Strength 500mg Cool Ice Caplet (36800-0010) (Topco Associates LLC)

Top Care Pain Relief Extra Strength 500mg Rapid Release Gelcap (36800-0046) (Topco Associates LLC)

Top Care Pain Relief Extra Strength 500mg Tablet (36800-0227) (Topco Associates LLC)

Tylenol 325mg Caplet (50580-0501) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Tylenol 325mg Caplet (50580-0501) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Tylenol 325mg Tablet (00045-0496) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) 

Tylenol Extra Strength 500mg Caplet (00045-0449) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg Caplet (50580-0451) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg Caplet (00045-0444) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Tylenol Extra Strength 500mg Caplet (00045-0449) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg Caplet (00045-0449) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg Caplet (00045-0449) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Tylenol Extra Strength 500mg Caplet (00045-0449) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg Cool Caplet (00045-0444) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg CrushableTablet (00045-0499) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg EZ Tab (00045-0422) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg Gelcap (50580-0468) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg Geltab (50580-0124) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market) 

Tylenol Extra Strength 500mg Rapid Release Gels (00045-0488) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol Extra Strength 500mg Tablet (50580-0499) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) (off market)

Walgreens Acetaminophen 325mg Tablet (00363-0104) (Walgreen Co) 

Walgreens Acetaminophen 500mg Caplet (00363-0175) (Walgreen Co) 

Walgreens Acetaminophen 500mg Extra Strength Cool Ice Caplet (00363-0010) (Walgreen Co) 

Walgreens Acetaminophen 500mg Extra Strength Tablet (00363-0148) (Walgreen Co) 

Walgreens Acetaminophen Extra Strength 500mg Easy Tab Tablet (00363-0531) (Walgreen Co) 

Walgreens Acetaminophen Extra Strength 500mg Fast Release QuickGels Gelcap (00363-0519) (Walgreen Co) 

Walgreens Acetaminophen Extra Strength 500mg Geltab (00363-0187) (Walgreen Co) 

XS Pain Reliever 500mg Tablet (54629-0915) (National Vitamin Company Inc)

XS Pain Reliever 500mg Tablet (54629-0965) (National Vitamin Company Inc)

XS Pain Reliever 500mg Tablet (54629-0966) (National Vitamin Company Inc)

Acetaminophen Oral tablet, biphasic release

RITE AID Acetaminophen 8 Hour 650mg Extended-Release Caplet (Rite Aid Corp)

Tylenol 8 Hour 650mg Extended Relief Caplet (00045-0297) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)

Tylenol 8 Hour 650mg Extended Relief Caplet (00045-0297) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)
Tylenol 8 Hour 650mg Extended Relief Geltab (50580-0505) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)
Tylenol Arthritis Pain 650mg Extended-Relief Caplet (00045-0838) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.) 

Acetaminophen Oral tablet, extended release

Acetaminophen 650mg Extended-Release Tablet (68084-0777) (American Health Packaging)
CVS 8 Hour Pain Relief 650mg Extended-Release Caplet (CVS Pharmacy, Inc) 
CVS Arthritis Pain Relief 650mg Extended-Release Caplet (CVS Pharmacy, Inc) 
CVS Arthritis Pain Relief 650mg Extended-Relief Caplet (CVS Pharmacy, Inc) 
CVS Arthritis Pain Relief 650mg Extended-Release Geltab (CVS Pharmacy, Inc) 
CVS Arthritis Pain Relief 650mg Extended-Release Geltab (CVS Pharmacy, Inc) 
GNP 8 Hour 650mg Extended-Release Caplet (46122-0062) (AmerisourceBergen Corporation)
GNP Arthritis Pain Relief 650mg Extended-Release Caplet (24385-0629) (AmerisourceBergen Corporation)
GNP Arthritis Pain Relief 650mg Extended-Release Caplet (46122-0170) (AmerisourceBergen Corporation)
GNP Pain Relief 650mg Extended-Release Caplet (24385-0629) (AmerisourceBergen Corporation)
GoodSense 8 Hour Pain Relief 650mg Extended-Release Caplet (00113-0217) (Goodsense a Division of Perrigo) 
GoodSense Arthritis Pain Relief 650mg Extended-Release Caplet (00113-0544) (Goodsense a Division of Perrigo)
Health Mart Arthritis Pain Relief 650mg Extended-Release Caplet (62011-0026) (McKesson Corporation) 
Leader 8 Hour Pain Reliever 650mg Extended-Release Caplet (37205-0477) (Cardinal Health, Inc.) 
Leader Arthritis Pain Reliever 650mg Extended-Release Geltab (37205-0662) (Cardinal Health, Inc.) 
Leader Arthritis Pain Reliever 650mg Extended-Release Geltab (37205-0662) (Cardinal Health, Inc.) 
Leader Arthritis Pain Reliever Extended-Release Caplet (37205-0034) (Cardinal Health, Inc.) 
Leader Arthritis Pain Reliever Extended-Release Caplet (37205-0034) (Cardinal Health, Inc.) 
Mapap Arthritis Pain 650mg Extended-Release Caplet (00904-5769) (Major Pharmaceuticals Inc)
Premier Value Acetaminophen 8 Hour 650mg Extended-Release Caplet (68016-0336) (Chain Drug Consortium, LLC)
Premier Value Arthritis Pain Relief 650mg Extended-Release Caplet (68016-0019) (Chain Drug Consortium, LLC) (off market)
Premier Value Arthritis Pain Relief 650mg Extended-Release Caplet (68016-0333) (Chain Drug Consortium, LLC)
Premier Value Arthritis Pain Relief 650mg Extended-Release Geltab (68016-0340) (Chain Drug Consortium, LLC) 
Premier Value Arthritis Pain Relief 650mg Extended-Release Geltab (68016-0340) (Chain Drug Consortium, LLC) 
Premier Value Non-Aspirin 8 Hour 650mg Extended-Release Caplet (68016-0019) (Chain Drug Consortium, LLC)
Publix Arthritis Pain Relief 650mg Extended-Release Caplet (56062-0544) (Publix Super Markets, Inc)
RITE AID Arthritis Pain Relief 650mg Extended-Release Caplet (Rite Aid Corp)
Select Brand Arthritis Pain Relief Extended-Release Caplet (15127-0332) (Select Brand) 
Sunmark 8 Hour Pain Relief 650mg Extended-Release Caplet (49348-0924) (McKesson Corporation) 
Sunmark Arthritis Pain Relief 650mg Extended-Release Caplet (49348-0921) (McKesson Corporation) 
Today's Health Arthritis Pain Relief 650mg Extended-Release Caplet (Todays Health, Inc)
Top Care 8 Hour Pain Relief 650mg Extended-Release Caplet (36800-0217) (Topco Associates LLC)
Top Care Arthritis Pain Relief 650mg Extended-Release Caplet (36800-0544) (Topco Associates LLC)

Top Care Arthritis Pain Relief 650mg Extended-Release Caplet (36800-0966) (Topco Associates LLC)	
Tylenol Arthritis Pain 650mg Extended Relief Geltab (50580-0292) (McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.)	
Walgreens Acetaminophen 8 Hour 650mg Extended-Release Caplet (00363-0336) (Walgreen Co)	
Walgreens Arthritis Pain Relief Extended-Release Caplet (00363-0333) (Walgreen Co)	
Walgreens Arthritis Pain Reliever 650mg Extended-Release Geltab (11917-0148) (Walgreen Co)	

Acetaminophen Rectal suppository

Acephen 120mg Rectal Suppository (00713-0118) (G and W Laboratories Inc)	
Acephen 325mg Rectal Suppository (00713-0164) (G and W Laboratories Inc)	
Acephen 650mg Rectal Suppository (00713-0165) (G and W Laboratories Inc)	
Acetaminophen 120mg Rectal Suppository (00364-7247) (Actavis Inc. formerly Watson Pharmaceuticals Inc) (off market)	
Acetaminophen 120mg Rectal Suppository (59439-0121) (Ascent Pediatrics, Inc. a Subsidiary of Medicis Corporation) (off market)	
Acetaminophen 120mg Rectal Suppository (52297-0118) (Cardinal Health)	
Acetaminophen 120mg Rectal Suppository (45802-0732) (Clay Park Labs Inc a Division of Perrigo Pharmaceuticals)	
Acetaminophen 120mg Rectal Suppository (52735-0717) (Family Pharmacy)	
Acetaminophen 120mg Rectal Suppository (00839-5999) (HL Moore Drug Exchange) (off market)	
Acetaminophen 120mg Rectal Suppository (00839-7838) (HL Moore Drug Exchange) (off market)	
Acetaminophen 120mg Rectal Suppository (00182-1662) (Ivax Corporation a Division of Teva USA) (off market)	
Acetaminophen 120mg Rectal Suppository (49348-0796) (McKesson Drug Company)	
Acetaminophen 120mg Rectal Suppository (00603-8042) (Qualitest Pharmaceuticals Inc) (off market)	
Acetaminophen 120mg Rectal Suppository (00536-1255) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)	
Acetaminophen 120mg Rectal Suppository (00677-0700) (United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical Industries, Inc.) (off market)	
Acetaminophen 325mg Rectal Suppository (00182-7001) (Ivax Corporation a Division of Teva USA) (off market)	
Acetaminophen 325mg Rectal Suppository (00536-1320) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)	
Acetaminophen 650mg Rectal Suppository (00364-2581) (Actavis Inc. formerly Watson Pharmaceuticals Inc) (off market)	
Acetaminophen 650mg Rectal Suppository (24385-0147) (AmerisourceBergen Corporation)	
Acetaminophen 650mg Rectal Suppository (59439-0122) (Ascent Pediatrics, Inc. a Subsidiary of Medicis Corporation) (off market)	
Acetaminophen 650mg Rectal Suppository (45802-0730) (Clay Park Labs Inc a Division of Perrigo Pharmaceuticals)	
Acetaminophen 650mg Rectal Suppository (00839-6001) (HL Moore Drug Exchange) (off market)	
Acetaminophen 650mg Rectal Suppository (00839-7839) (HL Moore Drug Exchange) (off market)	
Acetaminophen 650mg Rectal Suppository (00182-1095) (Ivax Corporation a Division of Teva USA) (off market)	
Acetaminophen 650mg Rectal Suppository (00603-8045) (Qualitest Pharmaceuticals Inc) (off market)	
Acetaminophen 650mg Rectal Suppository (00536-1260) (Rugby Laboratories a Division of The Harvard Drug Group, LLC) (off market)	
Acetaminophen 650mg Rectal Suppository (00677-1016) (United Research Laboratories, Inc. a subsidiary of Sun Pharmaceutical Industries, Inc.) (off market)	
CVS Children's Fever Reducing 120mg Rectal Suppository (59779-0579) (CVS Pharmacy, Inc)	
FeverAll 650mg Rectal Suppository (00472-1203) (Actavis Inc.) (off market)	

FeverAll 650mg Rectal Suppository (51672-2117) (Taro Pharmaceuticals USA Inc)

FeverAll Children's 120mg Rectal Suppository (00472-1201) (Actavis Inc.) (off market)

FeverAll Children's 120mg Rectal Suppository (51672-2115) (Taro Pharmaceuticals USA Inc)

FeverAll Infants' 80mg Rectal Suppository (00472-1200) (Actavis Inc.) (off market) 

FeverAll Infants' 80mg Rectal Suppository (51672-2114) (Taro Pharmaceuticals USA Inc)

FeverAll Jr.Strength 325mg Rectal Suppository (00472-1202) (Actavis Inc.) (off market)

FeverAll Jr.Strength 325mg Rectal Suppository (51672-2116) (Taro Pharmaceuticals USA Inc)

Mapap 120mg Rectal Suppository (00904-7692) (Major Pharmaceuticals Inc) (off market)

Top Care Children's Fever Reducer 120mg Rectal Suppository (Topco Associates LLC)

Acetaminophen Solution for injection

OFIRMEV 1000mg/100ml Solution for Injection (43825-0102) (Cadence Pharmaceuticals Inc)

Monitoring Parameters

- LFTs
- serum creatinine/BUN: in chronic use or acute toxicity

Lab Tests

Acetaminophen (serum)

Type of Level	Traditional Units	Scientific International Units	Comments
Therapeutic Concentration	10-20 mcg/mL	66-132 µmol/L	
Toxic Concentration, 4 hours post ingestion	> 150 mcg/mL	>992 µmol/L	These levels reflect acute toxicity only and should not be used to evaluate chronic toxicity
Toxic Concentration, 12 hours post ingestion	> 40 mcg/mL	> 264 µmol/L	These levels reflect acute toxicity only and should not be used to evaluate chronic toxicity

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