children's

ACETAMINOPHEN

tylenol

ALSO KNOWN AS TYLENOL, THE OVER-THE-COUNTER DRUG IS AS A PEDIATRIC PAIN RELIEVER/FEVER REDUCER.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Children's Acetaminophen (oral) can cause:

+ Severe liver damage
+ Severe skin reactions (skin reddening, blisters, and rash)

HOWEVER, THE FDA HAS APPROVED CHILDREN'S ACETAMINOPHEN FOR INTRAVENOUS USE IN CHILDREN 2 - 12 YEARS OF AGE.

Children's Acetaminophen (intravenous) can cause:

+ Nausea
+ Vomiting
+ Constipation
+ Pruritus (itchiness)
+ Agitation
+ Injection site pain
+ Edema peripheral
+ Anemia
+ Atelectasis (collapse or closure of a lung resulting in reduced or absent gas exchange)
+ Tachycardia (increased heart rate)
+ Abdominal pain
+ Diarrhea
+ Pyrexia (fever)
+ Hepatic enzyme increase
+ Headache
+ Rash
+ Stridor
+ Wheezing
+ Muscle spasm
+ Pain in extremity
+ Insomnia

+ Metabolism and nutrition disorders: hypoalbuminemia, hypokalemia, hypomagnesemia, hypophosphatemia, hypervolemia
+ Oliguria (low urine output)
+ Pulmonary edema (excessive liquid accumulation in the tissue and air spaces of the lungs)
+ Hypoxia (body or a region of the body is deprived of adequate oxygen supply at the tissue level)
+ Pleural effusion (accumulation of excessive fluid in the pleural space, the potential space that surrounds each lung)
+ Periorbital edema (puffy eyes)
+ Vascular disorders: hypertension (high blood pressure), hypotension (low blood pressure)

SOURCES FROM THE JOHNSON & JOHNSON CONSUMER INC. + FDA + FRESENIUS KABI USA, LLC

Pediatric Use: The effectiveness of acetaminophen for the treatment of acute pain and fever has not been studied in pediatric patients less than 2 years of age. The safety and effectiveness of acetaminophen in pediatric patients older than 2 years is supported by evidence from adequate and well-controlled studies in adults with additional safety and pharmacokinetic data for this age group. (8.4)

WHAT IS ACETAMINOPHEN?

FDA U.S. FOOD & DRUG ADMINISTRATION https://www.fda.gov/drugs/information-drug-class/acetaminophen

Acetaminophen is an active ingredient in hundreds of over-the-counter (OTC) and prescription medicines. It relieves pain and fever. Acetaminophen can also be combined with other active ingredients in medicines that treat allergy, cough, colds, flu, and sleeplessness. In prescription medicines, acetaminophen is found with other active ingredients to treat moderate to severe pain. Acetaminophen can cause serious liver damage if more than directed is used. The FDA has taken action to improve the safety of consumers when using acetaminophen.

OTC pediatric oral liquid drug products containing acetaminophen have been associated with overdoses due to medication errors that resulted in serious adverse events, including severe liver damage and death. In particular, there have been reports of overdose attributed to confusion between concentrated acetaminophen drops (80 milligrams (mg)/0.8 milliliters (mL) and 80 mg/mL) and acetaminophen oral liquid (160 mg/5 mL). In addition to overdoses due to dosing errors, there have been reports of overdose from accidental ingestion by children.

https://www.fda.gov/media/89475/download

Acetaminophen is a p-aminophenol derivative with analgesic and antipyretic activities. Although the exact mechanism through which acetaminophen exert its effects has yet to be fully determined, acetaminophen may inhibit the nitric oxide (NO) pathway mediated by a variety of neurotransmitter receptors including N-methyl-D-aspartate (NMDA) and substance P, resulting in elevation of the pain threshold. The antipyretic activity may result from inhibition of prostaglandin synthesis and release in the central nervous system (CNS) and prostaglandin-mediated effects on the heat-regulating center in the anterior hypothalamus.

https://pubchem.ncbi.nlm.nih.gov/compound/acetaminophen

ACETAMINOPHEN CONCERNS

National Library of Medicine https://medlineplus.gov/druginfo/meds/a681004.html

Taking too much acetaminophen can cause liver damage, sometimes serious enough to require liver transplantation or cause death. You might accidentally take too much acetaminophen if you do not follow the directions on the prescription or package label carefully, or if you take more than one product that contains acetaminophen.

To be sure that you take acetaminophen safely, you should

- not take more than one product that contains acetaminophen at a time. Read the labels of all the prescription and nonprescription medications you are taking to see if they contain acetaminophen. Be aware that abbreviations such as APAP, AC, Acetaminophen, Acetaminoph, Acetaminop, Acetamin, or Acetam. may be written on the label in place of the word acetaminophen. Ask your doctor or pharmacist if you don't know if a medication that you are taking contains acetaminophen.

- take acetaminophen exactly as directed on the prescription or package label. Do not take more acetaminophen or take it more often than directed, even if you still have fever or pain. Ask your doctor or pharmacist if you do not know how much medication to take or how often to take your medication. Call your doctor if you still have pain or fever after taking your medication as directed.

Acetaminophen is in a class of medications called analgesics (pain relievers) and antipyretics (fever reducers). It works by changing the way the body senses pain and by cooling the body.

Read the labels of all medication prior to administration.
Look for abbreviations (listed above) + take exactly as directed.

ACETAMINOPHEN OVERDOSE

National Library of Medicine https://medlineplus.gov/druginfo/meds/a681004.html

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at https://www.poisonhelp.org/help. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

If someone takes more than the recommended dose of acetaminophen, get medical help immediately, even if the person does not have any symptoms. Symptoms of overdose may include the following:

- unusual bleeding or bruising
- pain in the upper right part of the stomach
- yellowing of the skin or eyes
- flu-like symptoms
- extreme tiredness
- nausea
- vomiting
- loss of appetite
- sweating

If your child exhibits any of the above symptoms or takes too much Tylenol, seek medical help immediately. Call poison control helpline: 1-800-222-1222 or 911 if your child has collapsed, had a seizure, has trouble breathing, or can't be awakened.

TYPES OF PEDIATRIC TYLENOL

Active ingredient

Acetaminophen 160 mg in each 5 mL

Dye-Free Cherry

anhydrous citric acid, flavors, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, potassium sorbate, purified water, sorbitol solution, sucralose, sucrose, xanthan gum

Active ingredient

Acetaminophen 160 mg in each 5 mL*

Inactive ingredients

Cherry

anhydrous citric acid, FD&C red no. 40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Grape

anhydrous citric acid, D&C red no. 33, FD&C blue no. 1, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum