

CHILDREN ACETAMINOPHEN ORAL SOLUTION- acetaminophen liquid MAJOR PHARMACEUTICALS

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.

Active ingredient (per 5 mL teaspoonful)

Acetaminophen 160 mg

Purpose

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if:

- adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have liver disease.

Ask a doctor before use if you are taking the blood thinning drug warfarin.

When using this product: Do not exceed recommended dose.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed**
- find dose in chart below
- if possible, use weight to dose, otherwise use age
- dosage may be repeated every 4 hours, or as directed by a doctor
- do not give more than 5 doses in 24 hours

Weight (lbs)	under 24	24-35	36-47	48-59	60-71	72-95	over 95
Age (years)	under 2	2 to 3	4 to 5	6 to 8	9 to 10	11	12 to adult
Dosage Teaspoonful (tsp)	consult Physician	1 tsp (5 mL)	1 1/2 tsp (7.5 mL)	2 tsp (10 mL)	2 1/2 tsp (12.5 mL)	3 tsp (15 mL)	4 tsp (20 mL)

Inactive ingredients: artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Drug Facts

Active ingredient (per 5mL teaspoonful) Purpose
Acetaminophen 160 mg.....Pain Reliever / Fever Reducer

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• the common cold • toothache • premenstrual and menstrual cramps • temporarily reduces fever

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MAJOR® NDC 0904-7014-16

Children's Acetaminophen Oral Solution

Cherry Flavored

16 OZ (473 mL)

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

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Other information
• store at room temperature 15°- 30°C (59°-86°F)
• protect from freezing • protect from light
• **TAMPER-EVIDENT:** Do not use if foil seal over bottle opening is torn, broken or missing.
Pharmacist-Preserve and dispense in tight, light-resistant containers with a child resistant cap as defined in the USP.

Inactive ingredients: artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Code # L-157 Rev. 09/19 M-164 Re-order No. 701199

Lot# Exp. Date: 3 09047 01416 3

Distributed by: MAJOR PHARMACEUTICALS
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Questions or Comments? 1-800-616-2471

CHILDREN ACETAMINOPHEN ORAL SOLUTION

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7014
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7014-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2019	
2	NDC:0904-7014-20	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/01/2019	

Labeler - MAJOR PHARMACEUTICALS (191427277)

Revised: 3/2021

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