

ACETAMINOPHEN- acetaminophen liquid

A-S Medication Solutions

Acetaminophen

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

Acetaminophen, USP 160 mg

Purpose

Pain reliever/fever reducer

Uses

For the temporary relief of minor aches and pains associated with:

- the common cold
- flu
- sore throat
- headache
- toothache
- and to reduce fever

Warnings

Liver Warning

This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs that contain acetaminophen

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.

Sore throat warning

if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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 your child has liver disease.

Ask a doctor or pharmacist before use

if your child is taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear.

These could be signs of a serious condition.

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

Directions

- **this product does not contain directions or complete warnings for adult use**
- use only the enclosed dosing cup designed for use with this product
- if possible, use weight to dose, otherwise use age
- dose may be repeated every 4 hours, while symptoms persist, up to five times a day or as directed by a doctor

Weight (lbs.)	Age (years)	Dosage Teaspoonful (tsp)*
Under 24	Under 2	Consult a doctor
24 to 35	2 to under 4	5 mL (1 tsp)
36 to 47	4 to under 6	7.5 mL (1 1/2 tsp)
48 to 59	6 to under 9	10 mL (2 tsp)
60 to 71	9 to under 11	12.5 mL (2 1/2 tsp)
72 to 95	11 to under 12	15 mL (3 tsp)

* or as directed by a doctor

Other information

- Each 5 mL contains: Sodium 3 mg
- If dispensed, dispense in a tight, light resistant container with a child-resistant cap.

- Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F)

Inactive ingredients

Cherry Flavor, Citric Acid, FD&C Red No. 40, Glycerin, Polyethylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Sorbitol Solution, Sucralose.

Questions?

You may report side effects by calling Westminster M-F (9 a.m. to 5 p.m. EST), at 1-844-221-7294 or FDA at 1-800-FDA-1088.

HOW SUPPLIED

Product: 50090-6059

NDC: 50090-6059-0 118 mL in a BOTTLE, PLASTIC

ACETAMINOPHEN liquid



ACETAMINOPHEN			
acetaminophen liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-6059(NDC:69367-323)
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-6059-0	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/26/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/05/2021	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-6059)

Revised: 11/2023

A-S Medication Solutions