

ACETAMINOPHEN- acetaminophen liquid
Westminster Pharmaceuticals, LLC

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.

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.

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 69367-323-04

Children's
Acetaminophen
Liquid

160 mg/5 mL

Pain Reliever / Fever Reducer

Sugar Free / Alcohol Free

Aspirin Free

CHERRY FLAVOR

4 fl. oz. (118 mL)

Westminster
Pharmaceuticals

NDC 69367-323-04

Children's Acetaminophen Liquid

160 mg/5 mL

Pain Reliever / Fever Reducer
Sugar Free / Alcohol Free
Aspirin Free
CHERRY FLAVOR

4 fl. oz. (118 mL)

Lot:
Exp:

WP Westminster
Pharmaceuticals

Tamper-Evident: Do not use if foil seal over
bottle opening is torn, broken, or missing.



3 69367 32304 8
Manufactured For:
Westminster Pharmaceuticals, LLC
Nashville, TN 37217
Rev. 08/23

Drug Facts (continued)

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Lift Here for more *Drug Facts* ▲

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ACETAMINOPHEN

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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:69367-323-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2021	
2	NDC:69367-323-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/05/2021	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 9/2023

Westminster Pharmaceuticals, LLC