ACETAMINOPHEN- acetaminophen liquid
Westminster Pharmaceuticals, LLC

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:

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)

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.

Manufactured for:
Westminster Pharmaceuticals, LLC
Nashville, TN 37217
Rev. 08/23

Drug Facts (continued)

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.

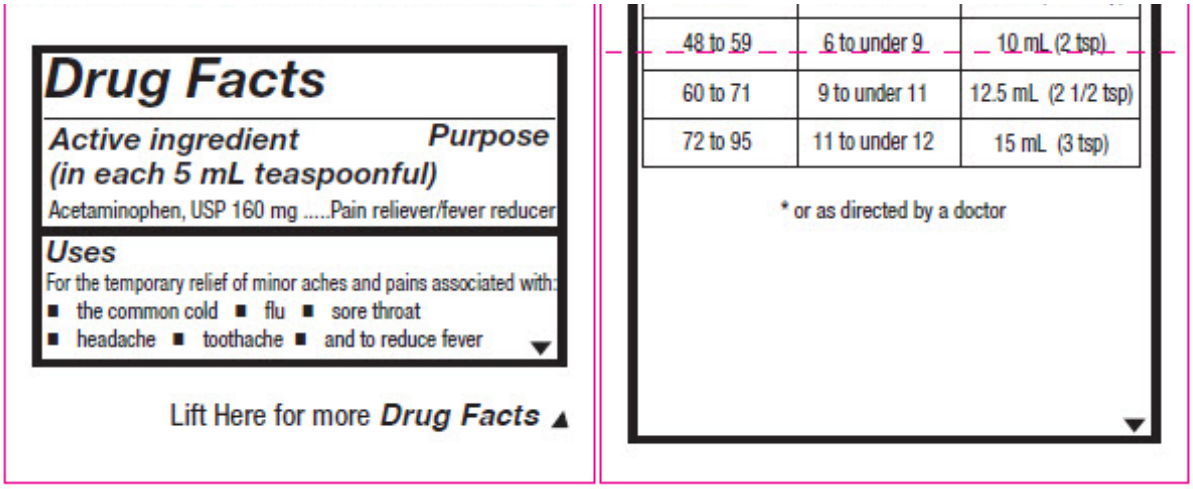
These could be signs of a serious condition.

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)



Drug Facts

Active ingredient (in each 5 mL teaspoonful) — **Purpose**

Acetaminophen, USP 160 mg .....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

Lift Here for more *Drug Facts*

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

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: 3WQ0SDW1A)	
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 DRUG	M013	05/05/2021	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 5/2021

Westminster Pharmaceuticals, LLC