

ACETAMINOPHEN- acetaminophen liquid
Oncor Pharmaceuticals

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 containing 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

- pain gets worse or lasts more than 5 day.
- fever gets worse or lasts more than 3 days
- redness or swelling is present.
- any new symptom 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 Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7600 or FDA at 1-800-FDA-1088.

Tamper-Evident:

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

Manufactured in USA for:

Oncor Pharmaceuticals
Columbia MD 21045

Rev. 01/2024

MADE IN USA

PRINCIPAL DISPLAY PANEL

ONCOR PHARMACEUTICALS

NDC 83720- 500-16

**Pain and
Fever Relief**

kids

**Acetaminophen
Liquid 160 mg / 5 mL**

Alcohol Free

Sugar Free

Aspirin Free

Ibuprofen Free

Cherry Flavor

16 fl. oz. - 473 mL


NDC 83720-500-16

Pain and Fever Relief

kids

Acetaminophen Liquid 160 mg / 5 mL

Alcohol Free

Sugar Free

Aspirin Free

Ibuprofen Free




16 fl. oz. - 473 mL

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

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 containing 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. ▶

Drug Facts (continued)

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 Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7600 or FDA at 1-800-FDA-1088.

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



3 83720 150016 117



Manufactured in USA for:
 Oncor Pharmaceuticals
 Columbia MD 21045
 Rev. 01/2024

Lot:
Exp:

ACETAMINOPHEN			
acetaminophen liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83720-500
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)		
	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:83720-500-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	04/10/2024	

Labeler - Oncor Pharmaceuticals (119032580)

Registrant - Oncor Pharmaceuticals (119032580)