

CHILDRENS ACETAMINOPHEN- acetaminophen elixir
We Care Distributor Inc.

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.

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/Fever reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
 - the common cold
 - flu
 - headache
 - sore throat
 - toothache

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

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 non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product

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

When using this product do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days

These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick 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.**
- **shake well before using**
- mL = milliliter
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor

Weight (lb.)	Age(yrs.)	Dose (mL*)
Under 24	Under 2	Ask a doctor
24-35	2-3	5 mL
36-47	4-5	7.5 mL
48-59	6-8	10 mL
60-71	9-10	12.5 mL
72-95	11	15 mL

* always check with your doctor before administering medicine to your infant/child

Other information

- **each teaspoon (5 mL) contains:** sodium 7 mg
- Store at room temperature 15° - 30°C (59° - 86°F)
- Protect from Freezing.
- Protect from Light.
- **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING**

Inactive ingredients

citric acid, FD&C red # 40, FD&C blue # 1, flavor, glycerin. PEG 400, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol

QUESTIONS OR COMMENTS

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

PRINCIPAL DISPLAY PANEL

*Compare to the active ingredient in Children's Tylenol® Elixir

Children's Acetaminophen Elixir
 Grape Flavor
 For ages 2 to 11
 2 FL OZ (60 mL)



Drug Facts (continued)
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**Contains one or more of these ingredient

NDC: 70005-049-01

CHILDREN'S ACETAMINOPHEN ELIXIR
 Pain Reliever / Fever Reducer

COMPARE TO ACTIVE INGREDIENT IN Children's Tylenol®*

Ages 2-11 Pain & Fever
 • Ibuprofen Free
 • Alcohol Free
 • Aspirin Free

Manufactured for/Distributed by:
 We Care Distributor Inc.
 Hermitage, TN 37078
 www.wecaredistributor.com

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Grape Flavor

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered Trademark Children's Tylenol® Elixir.

TAMPER EVIDENT: DO NOT USE this product if printed inner cap seal is broken or missing.

Drug Facts
Active ingredient Purpose (in each 5 mL)
 Acetaminophen 160 mg. Pain reliever/fever reducer.

Uses temporarily: ■ reduces fever
 ■ relieves minor aches and pains due to:
 ■ the common cold ■ flu ■ headache
 ■ sore throat ■ toothache

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Lot
 Exp

CHILDRENS ACETAMINOPHEN

acetaminophen elixir

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-049
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE (GRAPE)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-049-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/13/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	10/13/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
PURINE PHARMA LLC		019950491	manufacture(70005-049)

Revised: 10/2016

We Care Distributor Inc.