

**CHILDRENS ACETAMINOPHEN LIQUID- acetaminophen liquid**  
**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.*

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**Children's Acetaminophen Elixir**

Active Ingredient: Acetaminophen 160 mg (in each 5 mL)

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 wheather 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 or 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 for more than 5 days
- fever gets worse or lasts for 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 of 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)*
<b>Under 24</b>	<b>Under 2</b>	<b>Ask a doctor</b>
24-35	2-3	5mL
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 5 mL contains: sodium 7 mg**
- store between 15°-30°C (59°-86°F)
- protect from freezing
- protect from light

## Inactive ingredients

citric acid, FD&C red no. 40, flavor, glycerin, PEG 400, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol

## QUESTIONS & COMMENTS

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or [www.wecaredistributor.com](http://www.wecaredistributor.com)

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

Children's Acetaminophen Elixir

Cherry Flavor

For ages 2 to 11

2 FL OZ (60 mL)

This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Tylenol®.



## CHILDRENS ACETAMINOPHEN LIQUID

acetaminophen liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-048
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg in 5 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (cherry flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-048-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/12/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/11/2016	

**Labeler** - We Care Distributor Inc. (079832998)**Establishment**

Name	Address	ID/FEI	Business Operations
PURINE PHARMA LLC		019950491	manufacture(70005-048)

Revised: 10/2016

We Care Distributor Inc.