

## **CHILDRENS ACETAMINOPHEN- acetaminophen suspension**

**We Care Distributors 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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### **Drug Facts**

#### **Active Ingredient (in each 5 mL)**

Acetaminophen 160 mg

#### **Purpose**

Acetaminophen.....Pain reliever/fever reducer

#### **Uses**

- temporarily reduces fever
- temporarily 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 the reach of children.

**Overdose Warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. Quick medical attention is critical 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.
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- 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	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 (mL) contains: Sodium 3 mg**
- store between 15<sup>0</sup>-30<sup>0</sup>C (59<sup>0</sup>-86<sup>0</sup>F)
- Protect from freezing
- Protect from light

### Inactive Ingredients

butylparaben, carboxymethylcellulose sodium, cellulose, citric acid, corn syrup, FD&C red #40, flavor, glycerin, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol, sucralose, xanthan gum

### Questions or Comments?

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

## Principal Display Panel

Compare to the active ingredient in Children's Tylenol®\*  
 Children's Pain Relief  
 Suspension Liquid  
 Cherry Flavor  
 For ages 2 to 11  
 2 FL OZ (60 mL)

<b>Drug Facts (continued)</b>	NDC: 70005-041-01	NDC: 70005-041-01	<b>TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING</b>																					
<b>Overdose warning:</b> 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.	 <b>CHILDREN'S ACETAMINOPHEN ORAL SUSPENSION</b> <b>COMPARE TO ACTIVE INGREDIENT IN Children's Tylenol®*</b> Pain Reliever / Fever Reducer		<b>Drug Facts</b> <b>Active ingredient Purpose (in each 5 mL)</b> Acetaminophen 160 mg., Pain reliever/fever reducer																					
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<b>Other information</b> ■ each teaspoon (5 mL) contains: sodium 3 mg ■ Store between 15° - 30° C (59° - 86° F) ■ Protect from Freezing ■ Protect from Light	Manufactured for/Distributed by: We Care Distributor Inc. Hermitage, TN 37076 www.wecaredistributor.com		<b>Ask a doctor before use if your child has</b> liver disease <b>Ask a doctor or pharmacist before use if your child is</b> taking the blood thinning drug warfarin																					
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<b>Questions or comments?</b> 1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com	*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered Trademark Children's Tylenol® Suspension.		<b>Stop use and ask a doctor if</b> ■ 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. <b>Keep out of reach of children.</b>																					
**Contains one or more of these ingredient	<b>2 FL.OZ(60 mL) - 160 mg per 5 mL.</b>																							

## CHILDRENS ACETAMINOPHEN

acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70005-041
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg in 5 mL
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### Inactive Ingredients

Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (Cherry Flavor)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-041-01	1 in 1 CARTON	08/17/2016	
1		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/17/2016	

**Labeler** - We Care Distributors Inc. (079832998)

### Establishment

Name	Address	ID/FEI	Business Operations
PURINE PHARMA LLC		019950491	manufacture(70005-041)

