

CHILDRENS ACETAMINOPHEN ORAL SUSPENSION GRAPE FLAVOR-

acetaminophen suspension

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

Acetaminophen

160 mg.....Pain reliever/fever reducer

Uses

temporarily

- reduces fever
- 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.

Enter section text here

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 (yr)	Dose (tsp or 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 (5mL) contains: sodium 3 mg
- store between 15-30°C (59-86°F)
- protect from freezing
- protect from light

Inactive ingredients

butyl paraben, carboxymethylcellulose sodium, cellulose, citric acid, D&C red # 33, FD&C blue # 1, flavors, glycerin, high fructose corn syrup, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

QUESTIONS OR COMMENTS?

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

Principal Display Panel

Childrens Acetaminophen Oral Suspension

- Fever reducer
- Pain reliever

Alcohol Free

Aspirin Free

Ibuprofen Free

Grape Flavor

Compare to active ingredient in Childrens Tylenol Fever reducer Pain reliever

2 FL OZ (60 mL)

<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ 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. <table border="1"> <thead> <tr> <th>Weight (lb.)</th> <th>Age (yrs.)</th> <th>Dose (ml)*</th> </tr> </thead> <tbody> <tr> <td>Under 24</td> <td>Under 2</td> <td>Ask a doctor</td> </tr> <tr> <td>24-35</td> <td>2-3</td> <td>5mL</td> </tr> <tr> <td>36-47</td> <td>4-5</td> <td>7.5 mL</td> </tr> <tr> <td>48-59</td> <td>6-8</td> <td>10mL</td> </tr> <tr> <td>60-71</td> <td>9-10</td> <td>12.5mL</td> </tr> <tr> <td>72-95</td> <td>11</td> <td>15mL</td> </tr> </tbody> </table> <p>*always check with your doctor before administering medicine to your infant/child</p> <p>Other information</p> <ul style="list-style-type: none"> ■ each teaspoon (5 mL) contains: sodium 3 mg ■ Store between 15° - 30° C (59° - 86° F) ■ Protect from Freezing ■ Protect from Light <p>Inactive ingredients butylparaben, carboxymethylcellulose sodium, cellulose, citric acid, corn syrup, FD&C blue #1, FD&C red # 33, flavor, glycerin, microcrystalline cellulose**, propylene glycol, purified water, sodium benzoate, sucralose**, sorbitol, xanthan gum, sodium saccharin**</p> <p>Questions or comments? 1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com</p> <p>**Contains one or more of these ingredient</p>	Weight (lb.)	Age (yrs.)	Dose (ml)*	Under 24	Under 2	Ask a doctor	24-35	2-3	5mL	36-47	4-5	7.5 mL	48-59	6-8	10mL	60-71	9-10	12.5mL	72-95	11	15mL	<p>NDC: 70005-040-01</p>  <p>CHILDREN'S ACETAMINOPHEN ORAL SUSPENSION</p> <p>COMPARE TO ACTIVE INGREDIENT IN Children's Tylenol®*</p> <p>Pain Reliever / Fever Reducer</p> <p>Ages 2-11 Pain & Fever</p> <ul style="list-style-type: none"> • Ibuprofen Free • Alcohol Free • Aspirin Free <p>Manufactured for/Distributed by: We Care Distributor Inc. Hermitage, TN 37076 www.wecaredistributor.com</p>  <p>0 70005 04001 1</p>	<p>NDC: 70005-040-01</p>  <p>CHILDREN'S ACETAMINOPHEN ORAL SUSPENSION</p> <p>COMPARE TO ACTIVE INGREDIENT IN Children's Tylenol®*</p> <p>Pain Reliever / Fever Reducer</p> <p>Ages 2-11 Pain & Fever</p> <ul style="list-style-type: none"> • Ibuprofen Free • Alcohol Free • Aspirin Free <p>Grape Flavor</p>  <p>*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered Trademark Children's Tylenol® Suspension.</p> <p>2 FL OZ (60 mL) - 160 mg per 5 mL.</p>	<p>TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING</p> <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient (in each 5 mL)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Acetaminophen 160 mg.</td> <td>Pain reliever/fever reducer</td> </tr> </tbody> </table> <p>Uses temporarily: ■ reduces fever ■ relieves minor aches and pains due to: ■ the common cold ■ flu ■ headache ■ sore throat ■ toothache</p> <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes</p> <ul style="list-style-type: none"> ■ more than 5 doses in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen <p>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.</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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 <p>Ask a doctor before use if your child has liver disease</p> <p>Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin</p> <p>When using this product do not exceed recommended dose (see overdose warning)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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 <p>These could be signs of a serious condition.</p> <p>Keep out of reach of children.</p>	Active ingredient (in each 5 mL)	Purpose	Acetaminophen 160 mg.	Pain reliever/fever reducer
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CHILDRENS ACETAMINOPHEN ORAL SUSPENSION GRAPE FLAVOR

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-040
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
SODIUM BENZOATE (UNII: OJ245FE5EU)	
butylparaben (UNII: 3QPIU3FV8)	
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)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE (grape flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-040-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/26/2016	

Establishment

Name	Address	ID/FEI	Business Operations
PURINE PHARMA LLC		019950491	manufacture(70005-040)

Revised: 9/2016

We Care Distributor Inc.