

CHILDRENS ACETAMINOPHEN- acetaminophen suspension
R3 Pharmaceuticals, LLC

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.

Children's Acetaminophen Oral Suspension

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)

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 nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- 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

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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. (1-800-222-1222) Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- **do not give more than directed (see Liver and overdose warning)**
- **shake well before use**
- **this product does not contain directions or complete warnings for adult use**
- use only with enclosed dosing cup
- repeat dose every 4 hours if needed
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor
- find right dose on chart below. If possible, use weight to dose, otherwise; use age.

Weight (lb)	Age (yr)	Dose (tsp or mL)
under 24	under 2 years	ask a doctor
24-35	2-3 years	1 tsp or 5 mL
36-47	4-5 years	1 1/2 tsp or 7.5 mL
48-59	6-8 years	2 tsp or 10 mL
60-71	9-10 years	2 1/2 tsp or 12.5 mL
72-95	11 years	3 tsp or 15 mL

Other information

- **each teaspoon contains:** sodium 3 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

anhydrous citric acid, butylparaben, carboxymethylcellulose sodium, carrageenan, D&C red no. 33, FD&C blue no. 1, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol solution

Questions?

Call 601-859-0038

Distributed by: **R3 Pharmaceuticals, LLC**
Canton, MS 39046

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC 59999-001-04

SEE NEW WARNINGS INFORMATION

**Compare to the active ingredient in
Children's Tylenol[®] Oral Suspension**

**Children's
Acetaminophen
oral suspension**

**80 mg per 1/2 teaspoon
(160 mg per 5 mL)**

**fever reducer/
pain reliever**

AGE

2-11

YEARS

Grape Flavor

R3 Pharmaceuticals

4 FL OZ (118 mL)



NDC 59999-001-04

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(160 mg per 5 mL)

fever reducer/
pain reliever



4 FL OZ (118 mL)

DO NOT USE IF SEAL UNDER CAP IS
BROKEN OR MISSING

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)	Purpose
Acetaminophen 160 mg.....	Pain reliever/fever reducer

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

- Warnings**
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 - 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 nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
 - 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**
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 - fever gets worse or lasts more than 3 days
 - new symptoms occur
 - redness or swelling is present
- These could be signs of a serious condition.

Keep out of reach of children.

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Children's Acetaminophen

oral suspension

80 mg per 1/2 teaspoon
(160 mg per 5 mL)



Drug Facts (continued)

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NDC 59999-001-04

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

Children's Acetaminophen

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Questions? Call 601-859-0038

DO NOT USE IF PRINTED SAFETY SEAL IS BROKEN OR MISSING.

KEEP THIS BOX FOR COMPLETE INSTRUCTIONS.

Distributed by: **R3 Pharmaceuticals, LLC**
Canton, MS 39046

Rev. 8/2013

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

oral suspension

80 mg per 1/2 teaspoon
(160 mg per 5 mL)



fever reducer/
pain reliever



4 FL OZ (118 mL)



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3 59999-001-04 7

Lot No.:

Exp. Date:

CHILDRENS ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59999-001
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Route of Administration	ORAL
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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)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59999-001-04	1 in 1 CARTON		
1		118 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	09/23/2013	

Labeler - R3 Pharmaceuticals, LLC (078888843)

