

PAIN AND FEVER CHILDRENS- acetaminophen suspension

CVS Pharmacy

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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 dosage (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 (1-800-222-1222). 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**
- **do not take more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- if needed, 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
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.

Weight (lb)	Age (year)	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
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*or as directed by a doctor

Other information

- **each 5 mL contains:** sodium 2 mg
- store between 20-25°C (68-77°F)
- do not refrigerate
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, butylparaben, carboxymethylcellulose sodium, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

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

Oral Suspension

Children's

Pain and Fever

ACETAMINOPHEN 160 mg/5 mL

Pain reliever; Fever reducer

For Ages 2 to 11 Years

Free of: alcohol, aspirin, ibuprofen & gluten

DYE FREE

Grape flavor

FL OZ (mL)

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

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

Product Label

Drug Facts (continued)

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*or as directed by a doctor

Other information

■ each 5 mL contains: sodium 2 mg

■ store between 20-25°C (68-77°F)

■ do not refrigerate

■ see bottom panel for lot number and expiration date

Inactive ingredients

butylparaben, carboxymethylcellulose sodium, citric acid, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum

Questions or comments?

Call 1-877-753-3935 Monday-Friday 8AM-5PM EST

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CVS Health.

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

Oral Suspension

NDC 59779-785-08

Children's

Pain & Fever

ACETAMINOPHEN
160 mg/5 mL

Pain reliever; Fever reducer
For Ages 2 to 11 Years

Free of: alcohol, aspirin, ibuprofen & gluten

DYE FREE

Grape Flavor

8 FL OZ (237 mL)

Package Contains One Bottle

Actual Size

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Ask a doctor before use if your child has liver disease.

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Lot No.:
Exp. Date:

CVS HEALTH Children's Pain and Fever Grape Flavor

PAIN AND FEVER CHILDRENS

acetaminophen suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-785
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)				
BUTYLPARABEN (UNII: 3QPI1U3FV8)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
GLYCERIN (UNII: PDC6A3C0OX)				
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-785-08	1 in 1 BOX	08/31/2015	
1		237 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 Drug		M013	08/31/2015	

Labeler - CVS Pharmacy (062312574)