

## **PAIN AND FEVER CHILDRENS- acetaminophen suspension**

### **CVS Pharmacy**

*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**

**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
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- 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

<b>Weight (lb)</b>	<b>Age (year)</b>	<b>Dose (mL)*</b>
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

\*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

CVS.com

1-800-SHOP CVS

**Product Label**

**Drug Facts (continued)**

Find the right dose on chart below. If possible, use weight to dose; otherwise, use age.

Weight (lb)	Age (year)	Dose (mL)*
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72-95	11	15 mL

\*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, sucralose, xanthan gum

**Questions or comments?**  
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**Package Contains One Bottle**

Actual Size

**CVS Health.**

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

**Oral Suspension**

NDC 59779-785-06

**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)**

**Drug Facts**

**Active Ingredient (in each 5 mL)**  
Acetaminophen 160 mg.....Pain reliever/fever reducer

**Purpose**

**Uses**

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- 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).**

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- do not give more than 5 days unless directed by a doctor

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PLD-G2340 FC004026

Lot No.:  
Exp. Date:

CVS HEALTH Childrens Pain & Fever

<b>PAIN AND FEVER CHILDRENS</b>			
acetaminophen suspension			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-785
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<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

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYL PARABEN (UNII: 3QP1IU3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
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 NOT FINAL	part343	08/31/2015	

**Labeler** - CVS Pharmacy (062312574)

Revised: 10/2019

CVS Pharmacy