

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

**Freds Inc**

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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 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.**

**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 (1-800-222-1222) right away. 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**

acesulfame potassium, citric acid, butylparaben, carboxymethylcellulose sodium, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum

### **Questions or Comments?**

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

### **Principal Display Panel**

**\*\*Compare To Active Ingredients in Children's Tylenol® Oral Suspension\*\***

#### **Children's**

#### **Pain + Fever**

#### **Ages 2 - 11 Years**

ACETAMINOPHEN (160 mg per 5 mL)

Oral Suspension

Pain Reliever/Fever Reducer

Ibuprofen free

Aspirin free

Alcohol free

Cherry 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: fred's, Inc.**

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

**Product Label**

<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.</li> <li>if needed, repeat dose every 4 hours while symptoms last</li> <li>do not give more than 5 times in 24 hours</li> <li>do not give more than 5 days unless directed by a doctor</li> <li>find the right dose on chart below. 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If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if your child is allergic to acetaminophen or any of the inactive ingredients in this product.</li> </ul> <p><b>Ask a doctor before use if your child has liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.</b></p> <p><b>When using this product, do not exceed recommended dose (see Overdose warning).</b></p> <p><b>Stop use and ask a doctor if:</b></p> <ul style="list-style-type: none"> <li>new symptoms occur</li> <li>redness or swelling is present</li> <li>pain gets worse or lasts more than 5 days</li> <li>fever gets worse or lasts more than 3 days</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> Taking more than the recommended dose (overdose) may cause liver damage. 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DISTRIBUTED BY: fred's, Inc.  
4300 NEW GETWELL RD, MEMPHIS, TN 38118  
www.fredsinc.com

**100% satisfaction guaranteed**  
Questions or comments:  
1-855-331-FRED (3733)

0 84579 16075 4

PLD-12310 F004386

Lot No:  
Exp. Date:

**FRED'S PHARMACY Children's Pain and 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:55315-082
<b>Route of Administration</b>	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
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

**Product Characteristics**

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-082-04	1 in 1 BOX	12/31/2017	06/30/2024
1		118 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	12/31/2017	06/30/2024

**Labeler** - Freds Inc (005866116)