

CHILDRENS PAIN AND FEVER- childrens pain and fever suspension
PAI Holdings, LLC

Childrens Pain and Fever

Active ingredient

(in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/ fever reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pain 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 nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child has ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if 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 the 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:

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 sign or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give 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.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

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

*or as directed by a doctor

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

- **each 5 mL contains:** sodium 2 mg
- store at 20° to 25°C (68° to 77°F)
- **do not use if printed neckband is broken or missing**

Inactive ingredients:

acesulfame K, butylparaben, citric acid, D&C Red No. 33, FD&C Blue No. 1, flavoring, glycerin, high fructose corn syrup, polysorbate 80, propylene glycol, purified water, sodium benzoate, sorbitol solution, veegum and xanthan gum.

Questions or comments?**1-800-845-8210**

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

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V-38612**

Principal Display Panel

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

Suspension Liquid

NDC 0121-0973-08

Children's Pain & Fever**ACETAMINOPHEN****160 mg / 5 mL****Pain reliever; Fever reducer****Ages 2 to 11 years****Free of:**

- **Added Alcohol**
- **Aspirin**
- **Ibuprofen**

Grape Flavor

Use **ONLY** Enclosed Dosing Cup
 Actual Bottle Size on Side Panel
 8 FL OZ (237 mL)



CHILDRENS PAIN AND FEVER

childrens pain and fever suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-0973
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	

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:0121-0973-08	1 in 1 CARTON	11/21/2022	09/30/2024
1		237 mL in 1 BOTTLE; 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	11/21/2022	09/30/2024

Labeler - PAI Holdings, LLC (044940096)