

**PAIN AND FEVER RELIEF CHILDRENS- acetaminophen suspension**  
**Cardinal Health (Leader) 70000**

*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 nonprescription). 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

**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, D&C red #33, FD&C blue #1, flavors, 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**

Children's

**Pain & Fever**

Acetaminophen

160 mg per 5 mL

Oral Suspension

Fever Reducer, Pain Reliever

Grape Flavor

Ages 2-11 Years

Aspirin Free

Alcohol Free

Ibuprofen Free

FL OZ (mL)

COMPARE TO CHILDREN'S TYLENOL® ORAL SUSPENSION active ingredient\*\*

\*\*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 CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

**Product Label**

Drug Facts (continued)

Directions

■ this product does not contain directions or complete warnings for adult use

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■ shake well before using

■ mL = milliliter

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\*or as directed by a doctor

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Return to place of purchase if not satisfied.

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NDC 70000-0173-1

Children's Pain & Fever

Acetaminophen 160 mg per 5 mL

Oral Suspension  
Fever Reducer, Pain Reliever

Grape Flavor

Ages 2-11 Years

Alcohol Free  
Aspirin Free  
Ibuprofen Free

COMPARE TO CHILDREN'S TYLENOL® ORAL SUSPENSION active ingredient\*\*

100% Money Back Guarantee

4 FL OZ (118 mL)

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg.....Pain reliever/fever reducer

Purpose

Uses

■ temporarily reduces fever

■ temporarily relieves minor aches and pains due to:  
■ the common cold ■ flu ■ headache  
■ sore throat ■ toothache

Warnings

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■ with other drugs containing acetaminophen

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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 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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■ 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.

CIN 5294376 REV. 2/17

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PLD-B237D FC004035

Lot No.:

Exp. Date:

LEADER Children's Pain & Fever

PAIN AND FEVER RELIEF CHILDRENS

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0173
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: 3QPII03FV8)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
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:70000-0173-1	1 in 1 BOX	10/31/2016	12/31/2021
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 NOT FINAL		part343	10/31/2016	12/31/2021

**Labeler** - Cardinal Health (Leader) 70000 (097537435)