

PAIN AND FEVER RELIEF CHILDREN- 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.

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, flavor, 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 Dye-Free

Pain & Fever

Acetaminophen

160 mg per 5 mL

Oral Suspension

Fever Reducer, Pain Reliever

Free of: alcohol, aspirin and ibuprofen

Cherry flavor

Ages 2-11 Years

Alcohol Free

Aspirin 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 THE 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

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■ do not take more than directed (see Overdose warnings)

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*or as directed by a doctor

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Return to place of purchase if not satisfied.

LEADERTM

NDC 70000-0205-1

Children's Dye-Free

Pain & Fever

Acetaminophen 160 mg per 5 mL

Oral Suspension

Fever Reducer, Pain Reliever

Cherry 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

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CIN 5298757 REV. 11/16

UPC

0 96295 13054 6

PLD-A233D FC003784

Leader Children's Dye-Free Pain & fever Cherry Flavor

PAIN AND FEVER RELIEF CHILDREN

acetaminophen suspension

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0205 |
| 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 |
|-----------------|----------|
|-----------------|----------|

| | |
|--|--|
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| BUTYLPARABEN (UNII: 3QP1U3FV8) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| 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:70000-0205-1 | 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)

Revised: 11/2019

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