PAIN AND FEVER CHILDRENS- acetaminophen suspension Strategic Sourcing Services LLC

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

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 (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, 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 |
| | | |

*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

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 1-833-358-6431 Monday to Friday 9: am to 7:00 pm EST

Principal Display Panel

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

Children's

Pain Reliever

Acetaminophen 160 mg per 5 mL

Oral Suspension

Pain Reliever / Fever Reducer

Alcohol free

Aspirin free

Ibuprofen free

For ages 2-11 years

CHERRY FLAVOR

FL OZ (mL)

**This product is not manufactured or distributed by Johnson & Johnson Consumer Inc. McNeil Consumer Healthcare division, distributor f 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 McKesson Corp.,

via Strategic Sourcing Services LLC,

Memphis, TN 38141

Product Label



HEALTH MART Children's Pain Reliever Cherry Flavor

PLD-C231D FC007228 Product of China

PAIN AND FEVER CHILDRENS

acetaminophen suspension

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62011-0461 |
| Route of Administration | ORAL | | |
| | | | |
| | | | |

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

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311) | | |
| ACESULFAME POTASSIUM (UNII: 230V73Q5G9) | | |
| 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 | | | |

| P | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:62011- 0461-1 | 1 in 1 BOX | 09/22/2020 | | |
| 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 | 09/22/2020 | |
| | | | |

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 5/2024