

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

## **Kroger Company**

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### **Kroger Co. Children's Pain & Fever Drug Facts**

#### **Active ingredient (in each 5 mL)**

Acetaminophen 160 mg

#### **Purpose**

Pain reliever/fever reducer

#### **Uses**

temporarily:

- reduces fever
- 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 has ever had an allergic reaction to this product or any of its ingredients

**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**

- 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 signs 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

| <b>Weight (lb)</b> | <b>Age (yr)</b> | <b>Dose (mL)*</b> |
|--------------------|-----------------|-------------------|
| 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 3 mg
- store at 20-25°C (68-77°F)
- **do not use if printed neckband is broken or missing**

### Inactive ingredients

anhydrous citric acid, calcium sulfate, carrageenan, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

### Questions or comments?

**1-800-632-6900**

### Package/Label Principal Display Panel

COMPARE TO the active ingredient of CHILDREN'S TYLENOL® ORAL SUSPENSION

See side panel

Kroger®

OUR PHARMACIST RECOMMENDED

Age 2-11 Years

children's Pain & Fever

Acetaminophen 160 mg per 5 mL

Pain Reliever/Fever Reducer

Oral Suspension

Fast, Effective Relief of Children's Pain & Fever

Alcohol Free

Aspirin Free

Ibuprofen Free

DYE-FREE

Cherry Flavor

4 FL OZ (118 mL)



## CHILDRENS PAIN AND FEVER

acetaminophen suspension

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:30142-818 |
| <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 |
|---|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)                      |          |
| CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WAT0DDDB505)         |          |
| CARRAGEENAN (UNII: 5C69YCD2YJ)                                |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                   |          |
| HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)        |          |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)                 |          |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                           |          |
| WATER (UNII: 059QF0KO0R)                                      |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)                            |          |
| SORBITOL SOLUTION (UNII: 8KW3E207O2)                          |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                                  |          |
| SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)                 |          |

## Product Characteristics

|          |                        |              |  |
|----------|------------------------|--------------|--|
| Color    | WHITE (opaque,viscous) | Score        |  |
| Shape    |                        | Size         |  |
| Flavor   | CHERRY                 | Imprint Code |  |
| Contains |                        |              |  |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:30142-818-26 | 1 in 1 CARTON   | 02/12/2014           |                    |
| 1 |                  | 118 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                                     | 02/12/2014           |                    |

**Labeler** - Kroger Company (006999528)

