

TOPCARE CHILDRENS PAIN AND FEVER- acetaminophen suspension
Topco Associates LLC

Topco Associates LLC. 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

| 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 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, D&C red #33, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare® health

COMPARE TO CHILDREN'S TYLENOL® ORAL SUSPENSION ACTIVE INGREDIENT

children's

Pain & Fever

ORAL SUSPENSION

ACETAMINOPHEN, 160 mg per 5 mL

PAIN RELIEVER • FEVER REDUCER

FREE FROM:

- Aspirin
- Ibuprofen
- Alcohol
- Parabens

Ages 2 to 11 Years

BUBBLE GUM FLAVOR

4 FL OZ (118 mL)



| | | | |
|---|----------------|---------------------------|---------------|
| TOPCARE CHILDRENS PAIN AND FEVER | | | |
| acetaminophen suspension | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-699 |

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) | |
| CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WAT0DDB505) | |
| CARRAGEENAN (UNII: 5C69YCD2YJ) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| 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 (UNII: 506T60A25R) | |
| SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X) | |

Product Characteristics

| | | | |
|----------|--------------|--------------|--|
| Color | RED (opaque) | Score | |
| Shape | | Size | |
| Flavor | BUBBLE GUM | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:36800-699-26 | 1 in 1 CARTON | 08/26/1997 | |
| 1 | | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:36800-699-28 | 1 in 1 CARTON | 03/06/2013 | 01/31/2021 |
| 2 | | 148 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:36800-699-34 | 1 in 1 CARTON | 02/01/2024 | |
| 3 | | 236 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 | 08/26/1997 | |

Labeler - Topco Associates LLC (006935977)

Revised: 9/2024

Topco Associates LLC