

**CARING MILL CHILDRENS ACETAMINOPHEN- acetaminophen suspension
FSA Store Inc.**

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.

FSA Store Inc. Children's Acetaminophen 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, butylparaben, calcium sulfate, carrageenan, D&C red #33, FD&C blue #1, 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?

1-800-719-9260

Principal Display Panel

Age 2 to 11 Years

Children's Acetaminophen 160 mg per 5 mL

Pain Reliever/Fever Reducer

Oral Suspension Liquid

Grape Flavor

Ibuprofen Free

Alcohol Free

Aspirin Free

4 FL OZ (118 mL)



Drug Facts

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- 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

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Drug Facts (continued)

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Questions or comments?

1-800-719-9260

Manufactured by **FSA Store Inc.**

240 W. 37th St. 6th Floor
 New York, NY 10018
 Customer Care Help Line
 1-800-719-9260

caring mill™

caring mill™

Age 2 to 11 Years

Children's Acetaminophen 160 mg per 5 mL

Pain Reliever/Fever Reducer
 Oral Suspension Liquid

Grape Flavor



Ibuprofen Free
 Alcohol Free
 Aspirin Free

4 FL OZ (118 mL)

Fast, Effective Relief
 of Children's Pain
 and Fever

DIRECTIONS:
STEP 1.
 Shake well before using



STEP 2.
 Remove child protective cap



STEP 3.
 Squeeze your child's dose into the dosing cup



IMPORTANT:
 Please see dosing chart or ask a doctor for your child's correct dose.



CODE AREA

13026 JV C1

CARING MILL CHILDRENS ACETAMINOPHEN

acetaminophen suspension

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:81522-130 |
| 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: 3QPI1U3FV8) | |
| CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WATODDB505) | |
| CARRAGEENAN (UNII: 5C69YCD2YJ) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SORBITOL (UNII: 506T60A25R) | |
| SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X) | |

Product Characteristics

| | | | |
|----------|------------------|--------------|--|
| Color | PURPLE (viscous) | Score | |
| Shape | | Size | |
| Flavor | GRAPE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:81522-130-26 | 1 in 1 CARTON | 07/27/2021 | |
| 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 not final | part343 | 07/27/2021 | |

Labeler - FSA Store Inc. (049283340)

