SIGNATURE CARE CHILDRENS PAIN RELIEF- acetaminophen suspension Safeway

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.

Better Living Brands LLC Children's Pain Relief 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, 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?

1-888-723-3929

Principal Display Panel

Compare to Children's Tylenol® Oral Suspension active ingredient

Quality Guaranteed

FOR AGES 2 TO 11 YEARS

Children's Pain Relief

ORAL SUSPENSION ACETAMINOPHEN 160 mg per 5 mL

Pain Reliever/Fever Reducer

CHERRY FLAVOR

Ibuprofen Free

Aspirin free

Alcohol free

4 FL OZ (118 mL)



SIGNATURE CARE CHILDRENS PAIN RELIEF

acetaminophen suspension

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-243 Route of Administration ORAL Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
CALCIUM SULFATE (UNII: WAT0 DDB 505)		
CARRAGEENAN (UNII: 5C69 YCD2YJ)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SODIUM PHO SPHATE, TRIBASIC (UNII: A752Q30A6X)		

Product Characteristics			
Color	RED (opaque)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:21130-243-26	1 in 1 CARTON	09/28/2015		
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	09/28/2015	

Labeler - Safeway (009137209)

Revised: 8/2018 Safeway