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, 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

CHERRY FLAVOR

4 FL OZ (118 mL)



TOPCARE CHILDRENS PAIN AND FEVER acetaminophen suspension							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-557				
Route of Administration	ORAL						

Active Ingred		•		Deale of Churry		
		gredient Name		Basis of Streng		ength
ACETAMINOPHEN	(UNII: 362)	O9ITL9D) (ACETAMINOPHEN - UNII:362	D9ITL9D)	ACETAMINOPHEN	160 m	ig in 5 ml
Inactive Ingre	edients					
		Ingredient Name			St	rength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)						
CALCIUM SULFAT	E, UNSPE	CIFIED FORM (UNII: WAT0DDB505)				
CARRAGEENAN (U	NII: 5C69Y0	CD2YJ)				
FD&C RED NO. 40) (UNII: WZ	B9127XOA)				
GLYCERIN (UNII: PI	DC6A3C0O	X)				
HIGH FRUCTOSE	CORN SYR	UP (UNII: XY6UN3QB6S)				
HYDROXYETHYL (ELLULOS	E, UNSPECIFIED (UNII: T4V6TWG28D)			
MICROCRYSTALLI	NE CELLU	LOSE (UNII: OP1R32D61U)				
CARBOXYMETHYL	CELLULO	SE SODIUM, UNSPECIFIED (UNII: K6	790BS31	1)		
PROPYLENE GLYC	COL (UNII: 6	5DC9Q167V3)				
WATER (UNII: 059QF0KO0R)						
SODIUM BENZOATE (UNII: OJ245FE5EU)						
SODIUM BENZOA	TE (UNII: O	J245FE5EU)				
		*				
SORBITOL (UNII: 5	06T60A25F	*				
SORBITOL (UNII: 5	06T60A25F	3)				
SORBITOL (UNII: 5 SODIUM PHOSPH	06T60A25F ATE, TRIB /	ASIC (UNII: A752Q30A6X)				
SORBITOL (UNII: 5 SODIUM PHOSPHA Product Chara	06T60A25F ATE, TRIB /	ASIC (UNII: A752Q30A6X)				
SORBITOL (UNII: 5 SODIUM PHOSPH Product Char Color	06T60A25F ATE, TRIB /	ASIC (UNII: A752Q30A6X) ics RED (opaque)	Score			
SORBITOL (UNII: 5 SODIUM PHOSPH Product Char Color Shape	06T60A25F ATE, TRIB /	ASIC (UNII: A752Q30A6X) iCS RED (opaque)	Size			
SORBITOL (UNII: 5 SODIUM PHOSPH Product Char Color Shape	06T60A25F ATE, TRIB /	ASIC (UNII: A752Q30A6X) iCS RED (opaque)		Code		
SORBITOL (UNII: 5 SODIUM PHOSPHA Product Chara Color Shape Flavor	06T60A25F ATE, TRIB /	ASIC (UNII: A752Q30A6X) iCS RED (opaque)	Size	Code		
SORBITOL (UNII: 5 SODIUM PHOSPHA Product Chara Color Shape Flavor	06T60A25F ATE, TRIB /	ASIC (UNII: A752Q30A6X) iCS RED (opaque)	Size	Code		
SORBITOL (UNII: 5 SODIUM PHOSPH Product Char Color Shape Flavor Contains	06T60A25F ATE, TRIB /	ASIC (UNII: A752Q30A6X) iCS RED (opaque)	Size	Code		
SORBITOL (UNII: 5 SODIUM PHOSPH Product Char Color Shape Flavor Contains Packaging	06T60A25F ATE, TRIB /	ASIC (UNII: A752Q30A6X)	Size Imprint	keting Start	Marketi	
SORBITOL (UNII: 5 SODIUM PHOSPHA Product Chara Color Shape Flavor Contains Packaging # Item Code	06T60A25F ATE, TRIBA	ASIC (UNII: A752Q30A6X) ICS RED (opaque) CHERRY Package Description	Size Imprint Mai	keting Start Date	Da	
SORBITOL (UNII: 5 SODIUM PHOSPHA Color Shape Flavor Contains Packaging # Item Code	06T60A25F ATE, TRIBA	ASIC (UNII: A752Q30A6X) ICS RED (opaque) CHERRY Package Description	Size Imprint	keting Start Date		
SORBITOL (UNII: 5 SODIUM PHOSPHA Color Shape Flavor Contains Packaging # Item Code 1 NDC:36800-557-	06T60A25F ATE, TRIBA acterist	ASIC (UNII: A752Q30A6X) ICS RED (opaque) CHERRY Package Description	Size Imprint Mai 12/14/	keting Start Date	Da	
SORBITOL (UNII: 5 SODIUM PHOSPH Color Shape Flavor Contains Packaging # Item Code	06T60A25F ATE, TRIBA acterist 1 in 1 CAF 148 mL in Product	ASIC (UNII: A752Q30A6X) ICS RED (opaque) CHERRY Package Description RTON 1 BOTTLE; Type 0: Not a Combinatio	Size Imprint Mai 12/14/	Keting Start Date 1993 0	Da	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M013	12/14/1993			

Revised: 5/2024

Topco Associates LLC