

TOPCARE COLD- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl suspension

Topco Associates LLC

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.

Topco Associates LLC. Children's Pain Relief Plus Multi-Symptom Cold Drug Facts

Active ingredients (in each 5 mL)

Acetaminophen 160 mg

Chlorpheniramine maleate 1 mg

Dextromethorphan HBr 5 mg

Phenylephrine HCl 2.5 mg

Purposes

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves
- minor aches and pains
- headache
- minor sore throat pain
- runny nose
- itchy nose or throat
- sneezing
- itchy, watery eyes due to hay fever
- nasal and sinus congestion
- cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily reduces fever

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

- in a child under 4 years of age
- if your child has ever had an allergic reaction to this product or any of its ingredients
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
- to make a child sleepy

Ask a doctor before use if your child has

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

Ask a doctor or pharmacist before use if your child is taking

- sedatives or tranquilizers
- blood thinning drug warfarin

When using this product

- do not exceed recommended dosage
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. 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). Prompt 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
- remove the child protective cap and squeeze your child’s dose into the dosing cup
- may be given every 4 hours, while symptoms persist. Do not give more than 5 doses in 24 hours unless directed by a doctor.
- use enclosed dosing cup only. Keep for use with this product. Do not use any other dosing device.

Age	Dose
children under 4 years of age	do not use
children 4 to under 6 years of age	do not use unless directed by a doctor
children 6 to under 12 years of age	10 mL

Other information

- each 5 mL contains: sodium 3 mg
- contains no aspirin
- store at 20-25°C (68-77°F). Protect from light.
- close cap tightly

Inactive ingredients

anhydrous citric acid, calcium sulfate, carrageenan, D&C red #33, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, tribasic sodium phosphate, xanthan gum

Questions or comments?

1-888-423-0139

Principal Display Panel

COMPARE TO CHILDREN’S TRIAMINIC® MULTI-SYMPTOM FEVER & COLD

ACTIVE INGREDIENTS

TRIACTING SUSPENSION

children's Pain Relief Plus Multi-Symptom Cold

OUR PHARMACISTS RECOMMEND

FEVER REDUCER - PAIN RELIEVER - ACETAMINOPHEN

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr

NASAL DECONGESTANT - PHENYLEPHRINE HCl

ANTI-HISTAMINE - CHLORPHENIRAMINE MALEATE

Cold & Flu Symptom Relief

Runny & Stuffy Nose

Aches & Pains

Fever

Sore Throat

Cough

Ages 6 to under 12 Years

GRAPE FLAVOR

4 FL OZ (118 mL)



TOPCARE COLD

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-903-26
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
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE (opaque)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-903-26	1 in 1 CARTON	07/24/2009	
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 final	part341	07/24/2009	

Labeler - Topco Associates LLC (006935977)

