

TOPCARE CHILDRENS COLD AND COUGH- brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl solution

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 Cold and Cough Drug Facts

Active ingredients (in each 10 mL)

Brompheniramine maleate, USP 2 mg

Dextromethorphan HBr, USP 10 mg

Phenylephrine HCl, USP 5 mg

Purposes

Antihistamine

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold, and nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves these symptoms due to hay fever (allergic rhinitis):
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- to make a child sleepy

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease

- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- do not use more than directed
- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosage cup provided
- keep dosage cup with product
- mL = milliliter

age	dose
adults and children 12 years and over	20 mL every 4 hours
children 6 to under 12 years	10 mL every 4 hours
children under 6 years	do not use

Other information

- each 10 mL contains: sodium 4 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol solution

Questions or comments?

1-888-423-0139

Principal Display Panel

COMPARE TO CHILDREN'S DIMETAPP® COLD & COUGH ACTIVE INGREDIENTS

children's Cold & Cough

ANTIHISTAMINE – BROMPHENIRAMINE MALEATE

COUGH SUPPRESSANT – DEXTROMETHORPHAN HBr

NASAL DECONGESTANT – PHENYLEPHRINE HCl

Relieves Nasal Symptoms

Stuffy Nose

Runny Nose

Sneezing

OUR PHARMACISTS RECOMMEND

Plus Other Symptoms

Itchy, Watery Eyes

Cough

ALCOHOL FREE

Ages 6 Years and over

GRAPE FLAVOR

4 FL OZ (118mL)



TOPCARE CHILDRENS COLD AND COUGH

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-987
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)			BROMPHENIRAMINE MALEATE	2 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)			DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)			PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL
Inactive Ingredients				
Ingredient Name				Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBITOL (UNII: 506T60A25R)				
Product Characteristics				
Color	PURPLE (Clear bluish-red)		Score	
Shape			Size	
Flavor	GRAPE		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-987-26	1 in 1 CARTON	09/29/2006	
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		09/29/2006	

Labeler - Topco Associates LLC (006935977)