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

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 HCI

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)



Stuffv Nose

Runny Nose

Sneezing

Plus Other

Symptoms

Watery Eyes

ALCOHOL FREE

4 FL OZ (118 mL)

· Itchy,

Cough

Ages

and over

6 Years

+TopCare

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

children's Cold & Cough

ANTIHISTAMINE-BROMPHENIRAMINE MALEATE COUGHSUPPRESSANT-DEXTROMETHORPHAN HBr NASAL DECONGESTANT-PHENYLEPHRINEHCI

Relieves Nasal Symptoms

- Stuffy Nose
- Runny Nose
- Sneezing

Plus Other

Symptoms

· Itchv. **Watery Eyes**

 Cough ALCOHOL FREE



GRAPE FLAVOR





4 FL OZ (118 mL)



Drug Facts

Active ingredients (In each 10 mL)

Purposes

Brompheniramine maleate, USP 2 mg.....Antihistamine Dextromethorphan HBr, USP 10 mg...Cough suppressant Phenylephrine HCl, USP 5 mg......Nasal decongestant

IS BEOKEN OF MISSING DO NOT USE IF PRINTED NECKBAND www.StopMedicineAbuse.org rearn about teen medicine abuse :8ТИЗЯАЧ

Cold & Cough

Children's

® 97.6.⊃qoT**♣**

- been temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold, and nasal congestion due to the common cold, hay fever nasal congestion due to the common cold, hay fever or other upper respiratory allergiles

 temporarily relieves these symptoms due to hay fever (allergic rhinitis):

 unnyn cose

 necezing

 itchy, watery eyes

 thing 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
 In heart disease In high blood pressure
 In thyroid disease In diabetes
 In trouble urinating due to an enlarged prostate gland ■ glaucoma
 ■ cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or
- 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
- be careful when driving a motor vehicle or operating
- machinery

 excitability may occur, especially in children

Drug Facts (continued)

- Stop use and ask a doctor if
- 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
 accompanied by fever, rash, or persistent
 headache. A persistent cough may be a sign of a
 serious condition. 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?

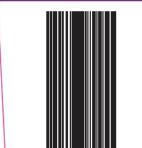
DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 ©TOPCO PER917 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com





This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

*This product is not manufactured or distributed by Pfizer, distributor of Children's Dimetapp® Cold & Cough.







LOT NO.

EXP.

: 98726 88 C4

TOPCARE CHILDRENS COLD AND COUGH

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl solution

Product Information

HUMAN OTC DRUG NDC:36800-987 **Product Type** Item Code (Source) **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: 1W5297W6MV) | 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 | | |

| F | 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 Drug | M012 | 09/29/2006 | |
| | | | |

Labeler - Topco Associates LLC (006935977)

Revised: 11/2024 Topco Associates LLC