

COUGH AND COLD HBP- chlorpheniramine maleate, dextromethorphan hbr tablet, film coated

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.

TopCare 44-689

Active ingredients (in each tablet)

Chlorpheniramine maleate 4 mg

Dextromethorphan HBr 30 mg

Purpose

Antihistamine

Cough suppressant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves runny nose and sneezing due to the common cold

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.

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with excessive phlegm (mucus)
- glaucoma
- a breathing problem or persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

persistent cough lasts for more than one week, tends to recur, or is accompanied by fever, rash, or

persistent headache. These could be signs 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 (1-800-222-1222) right away.

Directions

- **do not exceed recommended dose**
- adults and children 12 years and over: 1 tablet every 6 hours, not more than 4 tablets in 24 hours
- children under 12 years: do not use

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, D&C red #27 aluminum lake, FD&C yellow #6 aluminum lake, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare®

Health™

NDC 36800-689-21

**FOR PEOPLE WITH
HIGH BLOOD PRESSURE**

COMPARE TO CORICIDIN® HBP COUGH & COLD ACTIVE INGREDIENTS*

Cough & Cold HBP

CHLORPHENIRAMINE MALEATE
DEXTROMETHORPHAN HBr

ANTIHISTAMINE • COUGH SUPPRESSANT

Relieves:

- **Cough**
- **Runny Nose**
- **Sneezing**

•OUR PHARMACISTS RECOMMEND•

16 TABLETS

actual size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Coricidin® HBP COUGH & COLD.

50844 ORG111668921

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007 ©TOPCO LNKA0118

QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com

QUALITY GUARANTEED



Topcare 44-689

COUGH AND COLD HBP

chlorpheniramine maleate, dextromethorphan hbr tablet, film coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-689 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------|
| CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 4 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| D&C RED NO. 27 (UNII: 2LRS185U6K) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | RED | Score | no score |
| Shape | ROUND | Size | 9mm |
| Flavor | | Imprint Code | 44;689 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:36800-689-21 | 2 in 1 CARTON | 05/15/2017 | |
| 1 | | 8 in 1 BLISTER PACK; 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 | 05/15/2017 | |

Labeler - Topco Associates, LLC (006935977)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | MANUFACTURE(36800-689) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 832867837 | PACK(36800-689) |

Revised: 3/2020

Topco Associates, LLC