

SINUS AND ALLERGY RELIEF PE- chlorpheniramine maleate, phenylephrine hcl tablet

Topco Associates, LLC

TopCare 44-462

Active ingredients (in each tablet)

Chlorpheniramine maleate 4 mg

Phenylephrine HCl 10 mg

Purpose

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:
 - runny nose
 - sneezing
 - itching of the nose or throat
 - itchy, watery eyes
 - sinus congestion and pressure
 - nasal congestion

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

- high blood pressure
- heart disease
- thyroid disease
- diabetes
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever

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.

Directions

- adults and children 12 years and over: take 1 tablet every 4 hours. Do not take more than 6 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, lactose anhydrous, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

Questions or comments?

1-888-423-0139

Principal display panel

+TopCare®

health

NDC 36800-642-08

MAXIMUM STRENGTH

Sinus & Allergy Relief PE

CHLORPHENIRAMINE MALEATE 4 mg - ANTIHISTAMINE
PHENYLEPHRINE HCl 10 mg - NASAL DECONGESTANT

RELIEVES:

- Sneezing
- Runny Nose
- Nasal Congestion
- Sinus Congestion & Pressure
- Itching of the Nose or Throat
- Itchy, Watery Eyes

24 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

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

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QUESTIONS? 1-888-423-0139

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www.topcarebrand.com

50844 ORG031946208

QUALITY GUARANTEED

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-642
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	44;462
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-642-08	1 in 1 CARTON	07/02/2021	
1		24 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 Drug	M012	07/02/2021	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(36800-642)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(36800-642)

Revised: 7/2023

Topco Associates, LLC