

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

**Topco Associates, LLC**

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## **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**

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ELK GROVE VILLAGE, IL 60007

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QUESTIONS? 1-888-423-0139

topcare@topco.com

www.topcarebrand.com

50844 ORG031946208

**QUALITY GUARANTEED**

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



MAXIMUM STRENGTH

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- Sinus Congestion & Pressure
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actual size



No print/No varnish  
Lot & Exp date

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## Sinus & Allergy Relief PE

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

B-1910-462-08-R  
ORG031946208



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Scan here for more information or call 1-888-423-0139



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

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<b>Drug Facts</b> (continued)	<b>Drug Facts</b>
<b>Purpose</b> Chlorpheniramine maleate 4 mg, Antihistamine Phenylephrine HCl 10 mg, Nasal decongestant	<b>Uses</b> 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
<b>Warnings</b> 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, or a breathing problem such as emphysema or chronic bronchitis. Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.	<b>When using this product</b> do not exceed recommended dosage excitability may occur, especially in children
<b>Directions</b> 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	<b>Other information</b> TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN see end flap for expiration date and lot number store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
<b>Stop use and ask a doctor if</b> drowsiness may occur, avoid alcoholic beverages alcohol, sedatives and tranquilizers may increase drowsiness use caution when driving a motor vehicle or operating machinery	<b>Inactive ingredients</b> croscarmellose sodium, lactose anhydrous, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	<b>Questions or comments?</b> 1-888-423-0139

TopCare 44-462

## SINUS AND ALLERGY RELIEF PE

chlorpheniramine maleate, phenylephrine hcl tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-642
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

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

## Product Characteristics

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	07/02/2021	

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

**Establishment**

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

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(36800-642)

Revised: 7/2024

Topco Associates, LLC