

SINUS AND ALLERGY PE MAXIMUM STRENGTH- chlorpheniramine maleate and phenylephrine hydrochloride tablet, coated

American Sales Company

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.

CAR - 1133 - 2015-0401

Drug Facts

<i>Active ingredients (in each tablet)</i>	<i>Purpose</i>
Chlorpheniramine maleate 4 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant

Uses

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

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
- trouble urinating due to an enlarged 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**
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not improve within 7 days or occur with 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 (1-800-222-1222).

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 this product in children under 12 years of age

Other information

- store at 20°-25°C (68°-77°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, dibasic dicalcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, pregelatinized starch, sodium starch glycolate, stearic acid

PRINCIPAL DISPLAY PANEL

Compare to the Active Ingredients in Sudafed PE® Sinus & Allergy†

CareOne®

Sinus & Allergy PE

Chlorpheniramine Maleate, Antihistamine

Phenylephrine HCl, Nasal Decongestion

Maximum Strength

Sinus Pressure

Sinus & Nasal Congestion

Sneezing

Itchy, Watery Eyes

See New Dosing Directions

24 Tablets



SINUS AND ALLERGY PE MAXIMUM STRENGTH

chlorpheniramine maleate and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-602
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	T127
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-602-02	2 in 1 CARTON		
1		12 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	07/01/2011	

Labeler - American Sales Company (809183973)

