

ALLEREST PE- chlorpheniramine maleate and phenylephrine hydrochloride tablet
Insight Pharmaceuticals

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.

allerest® PE
PSEUDOEPHEDRINE FREE
ANTIHISTAMINE /
NASAL DECONGESTANT

Drug Facts

Active ingredients (in each tablet)

Chlorpheniramine Maleate 4 mg

Phenylephrine HCl 10 mg

Purposes

Antihistamine

Nasal Decongestant

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- nasal congestion
- itching of nose or throat

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

- heart disease
- high blood pressure
- thyroid disease
- glaucoma
- diabetes
- 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 use more than directed**
- drowsiness may occur
- avoid alcoholic drinks
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness effect
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better in 7 days or are accompanied by 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

- do not take more than 6 doses in 24 hours

adults and children 12 years and over	take 1 tablet every 4 hours
children 6 years to under 12 years	take 1/2 tablet every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years of age	do not use

Inactive ingredients

Cellulose, Corn Starch, Dicalcium Phosphate, Hypromellose, Magnesium Stearate, Mineral Oil, Silicon Dioxide, Starch Glycolate, Steric Acid.

QUESTIONS?

Call 1-800-344-7239 or write to

Consumer Affairs at the address below.

Distributed by: **INSIGHT Pharmaceuticals Corp.**
Langhorne, PA 19047-1749

PRINCIPAL DISPLAY PANEL - 18 Tablet Blister Pack Carton

PSEUDOEPHEDRINE FREE

allerest® PE

Chlorpheniramine Maleate/Antihistamine • Phenylephrine HCl/Nasal Decongestant

Allergy & Sinus Relief

Relieves:

- *Sinus Congestion & Pressure*
- *Sneezing, Itchy, Watery Eyes*
- *Nasal Congestion*

18 TABLETS

One Pill Per Dose

**Maximum Strength
Allergy and Sinus Relief
without Pseudoephedrine**

PSEUDOEPHEDRINE FREE
allerest PE
ANTIHISTAMINE / NASAL DECONGESTANT

Attention: Use only if tablet
blister seals are unbroken

PSEUDOEPHEDRINE FREE
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ANTIHISTAMINE /
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PSEUDOEPHEDRINE FREE
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LOT & EXP AREA

681880

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visit our website at www.insightpharma.com
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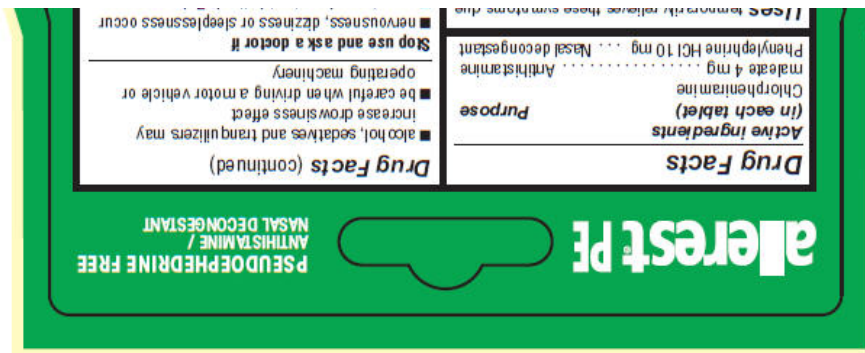
Inactive ingredients
colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, pregelatinized starch, sodium starch glycolate, stearic acid.

Other Information
Keep carton for full drug facts.
Store at room temperature 15° - 25°C (59° - 77°F).

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to under 12 years of age ask a doctor
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-586
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
Starch, Corn (UNII: O8232NY3SJ)	
Hypromelloses (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Mineral Oil (UNII: T5L8T28FGP)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	7mm
Flavor		Imprint Code	1;2;T;7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-586-18	1 in 1 BOX		
1		18 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2009	

Labeler - Insight Pharmaceuticals (176792315)

Revised: 1/2011

Insight Pharmaceuticals