

**CHLORPHENIRAMINE MALEATE - chlorpheniramine maleate tablet**  
**SDA Laboratories, Inc.**

*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.*

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**Drug Facts**

**Active ingredient(in each tablet)**

Chlorpheniramine Maleate 4 mg

**Purpose**

Antihistamine

**Uses**

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

- runny nose
- itchy nose or throat
- itchy watery eyes
- sneezing

**Warnings**

**Ask a doctor before use if you have,**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to enlarged prostate gland

**Ask a doctor or pharmacist before use if you**

are taking sedatives or tranquilizers

**When using this product**

- 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

**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 of age and older	one tablet 4 to 6 hours, not to exceed 6 tablets in 24 hours
children 6 to under 12 years of age	1/2 tablet every 4 to 6 hours, not to exceed 3 whole tablets in 24 hours
children under 6 years of age	consult a physician

### Other information

- **Tamper Evident:** Do not Use If Safety Seal Under Cap Is Broken Or Missing
- store at controlled room temperature 15<sup>o</sup>-25<sup>o</sup>C (59<sup>o</sup>-77<sup>o</sup>F)
- protect from excessive moisture

**Inactive ingredients: corn starch, croscarmellose sodium, D&C yellow # 10 aluminum lake 14-18%, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide**

### Questions:

**To Report Adverse Drug Events Call 800-687-0176.**

NDC 66424-034-10  
\*Compare to active ingredient in Chlor-Trimeton

**Chlorpheniramine Maleate Tablets, USP**  
**4 mg**

**ANTIHISTAMINE**  
**1000 TABLETS**

Not for households with young children

**SDA**  
LABORATORIES

**Drug Facts**

**Active ingredient (in each tablet)**  
Chlorpheniramine Maleate, 4 mg. . . . . Antihistamine

**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
 ■ runny nose ■ itchy nose or throat ■ itchy watery eyes ■ sneezing

**Warnings**  
**Ask a doctor before use if you have:**  
 ■ a breathing problem such as emphysema or chronic bronchitis  
 ■ glaucoma ■ trouble urinating due to enlarged prostate gland  
**Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.**  
**When using this product:**  
 ■ 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  
**If pregnant or breast-feeding, ask a health professional before use. Keep out of the reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

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**Inactive ingredients**  
 14-18%, croscarmellose sodium, D&C yellow #10 aluminum lake, corn starch, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, silicon dioxide

This Package Is Not For Households With Young Children.  
 Questions: To Report Adverse Drug Events Call 800-687-0176.  
 \*This product is not manufactured or distributed by Schering-Plough Healthcare Products Inc., owner of the registered trademark Chlor-Trimeton® 4 hour tablets.  
 Distributed by: SDA Laboratories, Inc., Greenwich, CT 06830  
 MADE IN USA  
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## CHLORPHENIRAMINE MALEATE

chlorpheniramine maleate tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66424-034
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

## Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

## Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	PH012
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66424-034-01	100 in 1 BOTTLE, PLASTIC		
2	NDC:66424-034-10	1000 in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/19/2010	

**Labeler** - SDA Laboratories, Inc. (948067889)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)

## Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture