

## **CHLORPHENIRAMINE MALEATE- chlorpheniramine maleate tablet**

### **Contract Pharmacy Services-PA**

*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.*

-----

### **Drug Facts 097**

#### **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 °-25 °C (59 °-77 °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.

<p><b>CHLORPHENIRAMINE</b> <b>4 MG TAB #30</b></p>  <p>016103346112</p> <p>LOT: P12G220 PILL ID: PH 012 EXP:02/22/14 PHARBEST</p> <p>Packaged By: Contract Pharmacy Services-PA 125 Titus Ave, Suite #200, Warrington, PA 18976</p>	<p>Do not exceed 6 doses in 24 hrs. Adults &amp; children 12 yrs of age &amp; older: 1 tablet every 4 to 6 hrs.</p>  <p>0 16103 34611 2</p> <p>Store at controlled room temperature 15°-30°C (59°-86°F)</p> <p>Each tablet contains: Chlorpheniramine Maleate 4 mg</p> <p>CPS NDC: 67046-097-30</p>
--	--

## CHLORPHENIRAMINE MALEATE

chlorpheniramine maleate tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67046-097(NDC:66424-034)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE 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**

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	PH012
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-097-14	14 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
2	NDC:67046-097-07	7 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
3	NDC:67046-097-15	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
4	NDC:67046-097-21	21 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
5	NDC:67046-097-28	28 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
6	NDC:67046-097-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
7	NDC:67046-097-60	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	

**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 final	part341	09/19/2017	

**Labeler** - Contract Pharmacy Services-PA (945429777)

**Establishment**

Name	Address	ID/FEI	Business Operations
Coupler Enterprises		945429777	repack(67046-097)

Revised: 9/2017

Contract Pharmacy Services-PA