

ALLERGY TIME - chlorpheniramine maleate tablet
State of Florida DOH Central Pharmacy

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.

Active ingredient (in each tablet) Chlorpheniramine maleate 4 mg

Purpose: Antihistamine>

Uses: temporarily relieves the following symptoms due to hay fever or other upper respiratory allergies:

runny nose, sneezing, itching of the nose or throat, itch, watery eyes

Warnings

Ask a doctor before use if you have:

glaucoma; a breathing problem such as emphysema or chronic bronchitis; difficulty urinating due to an 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 operating machinery

If pregnant or breast-feeding ask a health professional before use.

Directions

Adults and children 12 years and over - 1 tablet every 4 to 6 hours, not to exceed 6 tablets in 24 hours

Children 6 to under 12 years of age - 1/2 tablet (break tablet in half) every 4 to 6 hours, not to exceed 3 whole tablets in 24 hours

Children under 6 years of age - do not use

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

anhydrous lactose, colloidal silicon dioxide, croscarmellose sodium, D-C yellow #10 aluminum lake, magnesium stearate, microcrystalline cellulose, stearic acid.

This Product was Repackaged By:

State of Florida DOH Central Pharmacy

104-2 Hamilton Park Drive

Tallahassee, FL 32304

United States



ALLERGY TIME

chlorpheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53808-0880(NDC:49483-242)
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	yellow	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	TCL242
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-0880-2	60 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2013	

Labeler - State of Florida DOH Central Pharmacy (829348114)

Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack(53808-0880)

Revised: 9/2013

State of Florida DOH Central Pharmacy