

ALLERGY TIME- chlorpheniramine maleate tablet

Time Cap Labs 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.

242R CHLOR MAL

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.

Drug Facts (continued)
 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
- 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 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	½ 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

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from excessive moisture
- use by expiration date on package

Inactive ingredients anhydrous lactose, colloidal silicon dioxide, croscarmellose sodium, D&C Yellow #10 aluminum lake, magnesium stearate, microcrystalline cellulose, stearic acid

STOP PEELING

Adhesive Area

NDC 49483-242-01

Time-Cap Labs, Inc.
 Compare to the active ingredient in Chlor-Trimeton®*

Allergy-Time
 CHLORPHENIRAMINE MALEATE ANTIHISTAMINE

4 HOUR

Allergy Relief:

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat

100 TABLETS (4 MG EA)

Drug Facts

Active ingredient (in each tablet) Purpose
 Chlorpheniramine maleate 4 mg..... Antihistamine

Uses
 Temporarily relieves the following symptoms due to hay fever or other upper respiratory allergies:
 runny nose
 itching of the nose or throat
 sneezing
 itchy, watery eyes

Warnings
 Ask a doctor before use if you have
 a breathing problem such as emphysema or chronic bronchitis
 difficulty urinating due to an enlarged prostate gland

LOT #:
EXP. DATE:

PEEL HERE FOR MORE DRUG FACTS

*This product is not manufactured or distributed by the owner of the registered trademark Chlor-Trimeton®.
 Manufactured by:
 Time-Cap Labs, Inc.
 7 Michael Avenue
 Farmingdale, NY 11735
 242R 1009

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

ALLERGY TIME

chlorpheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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)	
CROSCARMELOSE 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:49483-242-00	100000 in 1 CARTON; Type 0: Not a Combination Product	12/17/2018	
2	NDC:49483-242-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
3	NDC:49483-242-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
4	NDC:49483-242-24	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/08/2011	

Labeler - Time Cap Labs Inc (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
Time Cap Labs Inc		037052099	manufacture(49483-242)

Revised: 12/2018

Time Cap Labs Inc