CHLORPHENIRAMINE MALEATE- chlorpheniramine maleate tablet
DIRECT RX

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.

CHLORPHENIRAMINE MALEATE

OTC - ACTIVE INGREDIENT SECTION

Chlorpheniramine maleate 4 mg

OTC - PURPOSE SECTION

Antihistamine

INDICATIONS & USAGE SECTION

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

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

- Do not use
  to make a child sleepy.
  Ask a doctor before use if you have
  - a breathing problem such as emphysema or chronic bronchitis
  - glaucoma
  - trouble 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
  - drowsiness may occur
  - avoid alcoholic beverages
  - alcohol, sedatives, and tranquilizers may increase drowsiness
  - use caution when driving a motor vehicle or operating machinery
  - excitability may occur, especially in children

  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 (1-800-222-1222) right away.

DOSAGE & ADMINISTRATION SECTION

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adults and children 12 years of age	1 tablet every 4 to 6

12 years of age and over	hours. Do not take more than 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. Do not exceed 3 whole tablets in 24 hours.
children under 6 years of age	do not use this product in children under 6 years of age

INFORMATION FOR PATIENTS SECTION

- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- protect from excessive moisture
- see end flap for expiration date and lot number

INACTIVE INGREDIENT SECTION

- corn starch, D&C yellow #10 aluminum lake, lactose anhydrous, magnesium stearate, microcrystalline cellulose

OTC - QUESTIONS SECTION

(800) 616-2471

WARNINGS SECTION

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to make a child sleepy.

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

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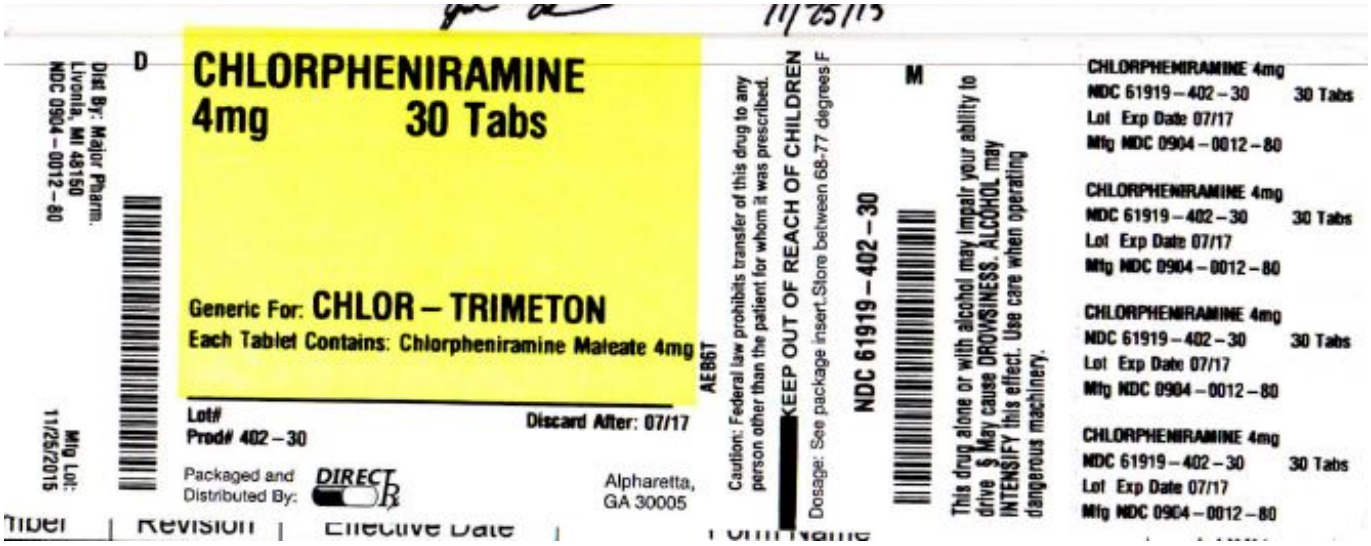
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



CHLORPHENIRAMINE MALEATE

chlorpheniramine maleate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-402(NDC:0904-0012)
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)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	yellow	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	44;194
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-402-71	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/2014	
2	NDC:61919-402-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2014	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(61919-402) , repack(61919-402)