

ALLERGY- chlorpheniramine maleate tablet

Major Pharmaceuticals

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.

Major 44-194

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, watery eyes
- sneezing
- itching of the nose or throat

Warnings

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.

Directions

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

Other information

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

Inactive ingredients

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

Questions or comments?

(800) 616-2471

Principal Display Panel

MAJOR®

NDC 0904-0012-59

***Compare to the active ingredient in Chlor-Trimeton® Allergy Tablets**

Allergy Tablets

Chlorpheniramine maleate 4 mg EACH
ANTI-HISTAMINE

Relieves:

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

4 hour

100 TABLETS

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by MSD Consumer Care, Inc., owner of the registered trademark Chlor-Trimeton® Allergy Tablets.
50844 REV0213L19412

Distributed by **MAJOR® PHARMACEUTICALS**
31778 Enterprise Drive, Livonia, MI 48150 USA
Rev. 12/14 Re-order No. 700459 M-17

REV0213L19412

B-1212-194-12

No print/No varnish
Lot & Exp date

3 090401101259 3

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

REV0213L19412

Drug Facts (continued)

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31778 Enterprise Drive, Livonia, MI 48150 USA
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4 hour

ANTHISTAMINE

Allergy Tablets

Chlorpheniramine maleate 4 mg EACH

100 TABLETS

Relieves:
• Sneezing • Itchy, Watery Eyes
• Itchy Throat • Runny Nose

Compare to the active ingredient in Chlor-Trimeton® Allergy Tablets

NDC 0904-0012-59

MAJOR®

4 hour

ANTHISTAMINE

Allergy Tablets

Chlorpheniramine maleate 4 mg EACH

100 TABLETS

Drug Facts KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each tablet)	Purpose
Chlorpheniramine maleate 4 mg . . . Anthistamine	
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> <li style="width: 50%;">■ runny nose <li style="width: 50%;">■ itchy, watery eyes <li style="width: 50%;">■ sneezing <li style="width: 50%;">■ itching of the nose or throat 	
Warnings Do not use to make a child sleepy.	
Ask a doctor before use if you have <ul style="list-style-type: none"> <li style="width: 50%;">■ a breathing problem such as emphysema or chronic bronchitis <li style="width: 50%;">■ glaucoma <li style="width: 50%;">■ 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 <ul style="list-style-type: none"> ■ 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 	

Major 44-194

ALLERGY
chlorpheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

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:0904-0012-61	10 in 1 CARTON	12/19/1992	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-0012-24	2 in 1 CARTON	12/19/1992	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0904-0012-59	1 in 1 CARTON	12/19/1992	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0904-0012-80	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/19/1992	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/19/1992	

Labeler - Major Pharmaceuticals (191427277)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0904-0012)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0904-0012)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0904-0012)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0904-0012)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0904-0012)

Revised: 3/2019

Major Pharmaceuticals