

ANTI ALLERGY- chlorpheniramine maleate tablet
Advance Pharmaceutical 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.

Anti-Allergy Tablets Antihistamine

Active Ingredient

(in each tablet)

Chlorpheniramine Maleate 4 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms of hay fever or other upper respiratory allergies :

- runny nose
- itchy nose or throat
- sneezing
- itchy, watery eyes

Warnings

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives & tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating a machine
- 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 right away.

Directions [S]

Adults & children 12 years and over	take 1 tablet every 4 to 6 hours, not more than 6 tablets in 24 hours
children 6 years to under 12	take ½ tablet every 4 to 6 hours not more than 3 tablets in 24 hours

years
children under 6 years

do not use

hours

Other Information

- each tablet contains: calcium 40 mg
- store between 15°-30°C (59°-86°F)
- protect from moisture

Inactive Ingredients

croscarmellose sodium, D&C yellow #10 (al-lake), dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, starch

Questions or Comments

Call **1-800-645-2158**, 8.30 am – 4.30 pm ET, Monday - Friday

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR BLISTER UNIT IS
BROKEN OR DAMAGED**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



Advance
Pharmaceutical Inc.

100 TABLETS

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

Chlorpheniramine Maleate 4 mg.

Antihistamine

Anti-Allergy
Tablets

NDC 17714-016-01
*Compare to active ingredient in Chlor-Trimeton®

Drug Facts

**Active ingredient
(in each tablet)**

Purpose

Chlorpheniramine maleate 4 mg ... Antihistamine

Uses temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy nose or throat
- itchy, watery eyes

Warnings

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness

Drug Facts continued on back of label

*Advance Pharmaceutical Inc. is not affiliated with the owners of the trademark Chlor-Trimeton®.

Manufactured by: **Advance Pharmaceutical Inc.**
Holtsville, NY 11742, USA

Lot No.:

Exp. Date:

LA1112



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Drug Facts (continued)

- be careful 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 right away.

Directions

adults and children 12 years and over	take 1 tablet every 4 to 6 hours, not more than 6 tablets in 24 hours
children 6 years to under 12 years	take 1/2 tablet every 4 to 6 hours, not more than 3 tablets in 24 hours
children under 6 years	do not use

Other information

- **each tablet contains:** calcium 40 mg
- store at 15°-30°C (59°-86°F)
- protect from moisture

Inactive ingredients

croscarmellose sodium, D&C yellow# 10 (Al-lake), dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, starch

Questions or comments?

call **631-981-4600**, 8:30 am - 4:30 pm ET, Monday - Friday

**Chlorpheniramine Maleate 4 mg
Antihistamine**

17714-016-01 100 Tablets

ANTI ALLERGY

chlorpheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17714-016
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	yellow (light yellow)	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	AP;016
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17714-016-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/09/2002	
2	NDC:17714-016-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/09/2002	

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(17714-016)

Revised: 10/2017

Advance Pharmaceutical Inc.