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 Antihis tamine

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

years hours

children under 6 years

do not use

Other Information

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

Inactive Ingredients

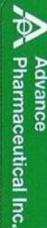
croscarmellose sodium, D&C yellow #10 (al-lake), dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, starch

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



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

Drug Facts Active ingredient (in each tablet)

Purpose

Chlorpheniramine maleate 4 mg ... Antihistamine

Chlorpheniramine Maleate 4 mg

Antihistamine

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

100 TABLETS

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





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 take 1 tablet every children12 years 4 to 6 hours, not more than 6 tablets and over in 24 hours take 1/2 tablet children 6 years to under 12 years every 4 to 6 hours, not more than 3 tablets in 24 hours do not use children under 6 years 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 Antihis tamine

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		

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
STARCH, CORN (UNII: O8232NY3SJ)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			

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

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	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	12/0 1/20 12	

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)

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

Revised: 10/2017 Advance Pharmaceutical Inc.