CHLORPHENIRAMINE MALEATE - chlorpheniramine maleate tablet, film coated, extended release

Cardinal Health, Inc.

Unknown Title

Chlorpheniramine maleate 12 mg

Antihis tamine

USES

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

WARNINGS

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

excitability may occur, especially in children drowsiness may occur avoid alcoholic beverages

alchohol, sedatives and tranquilizers may increase drowsiness use caution when driving a motor vehicle or operating machinery

Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088

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 12 hours. Do not exceed 2 tablets in 24 hours. children under 12 years of age: ask a doctor

OTHER INFORMATION

each tablet contains: calcium 28 mg

store between 20° to 25° C (68° to 77° F) with excursions permitted between 15° to 30° C (59° to 86° F)

protect from excessive moisture

INACTIVE INGREDIENTS

calcium sulfate, carnauba wax, colloidal silicon dioxide, confectioner's sugar, D&C yellow No. 10 aluminum lake, FD&C blue No. 2/indigo carmine aluminum lake, FD&C yellow No. 6, gelatin, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, methacrylic acid copolymer, methyl parahydroxybenzoate, microcrystalline cellulose, pharmaceutical ink, polysorbate 80, povidone, propyl parahydroxybenzoate, propylene glycol, sodium benzoate, sodium lauryl sulphate, sucrose, talc, titanium dioxide, triethyl citrate

PURPOSE

Chlorpheniramine maleate 12 mg is used as an antihistamine.

Manufactured by:

KVK-Tech, Inc. Newtown, PA 18940



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 37205-117-62 Allergy Tablets

Chlorpheniramine maleate 12 mg



ASU NI 30AM Manufactured by KVK-TECH, INC. Newtown, PA 18940. f pregnant or breast-feeding, ask a health Call your doctor for medical advice about side effects.
You may report side effects to FDA at **1-800-FDA 1088** This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., distributor of Chlor-Trimeton®. When using this product a soxialibility may occur, when using this product a soxialibility may occur, a sovial siconity of conflicter may increase also holo, seadaives, and a morphility and yoccur as a conflicter may increase drowsiness a use caulion when driving a motor value of soxiality of conflicters may increase drowsiness as use caulion when driving a motor value as conficient and driving a motor value of soxiality and confice or present of the confice of the c Inactive ingredients calcum sulfate, cancular was a cancular was a collection double connection was collection double confidence and collection double collection double collection of collection collections and collections in state of copylman feet and collections and collections and collections and collections and collections of collections of collections and collections and collections and collections and collections are collected and collecti Ask a doctor or pharmacist before use if you are
at sking sedatives or tranquilizers COATING FREE AREA Jak a doctor before use if you have ■ a breathing broblem such as emphysema or chronic bronchitis ■ glaucoma ■ glaucoma | touble urinating due to an enlarged prostate gland COATING FREE Marnings **USGS** • temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

Intensy nose • technical watery eyes

Intensy nose • throat Directions

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every 12 hours, bo not exceed 2 tablets in 24 hours.

a children under 12 years of age: ask a doctor

- children under 12 years of age: ask a doctor Active ingredient (in each tablet)...Purpose Drug Facts **Ceep out of reach of children.** In case of overdose, get nedical help or contact a Poison Control Center right awa 12-hour relief TI. aniore henifiariilne maleate Drug Facts (continued) Allergy Tablets **Allergy Tablets** 12 Chlorpheniramine maleate
Antihistamine
12-hour relief SAFETY SEALED: DO NOT USE IF BACKING IMPRINTED WITH Chlorpheniramine Maleate Exter THIS PACKAGING IS NOT CHILD RESISTANT Tablets, 12 mg IS TORN OR MISSING NDC 37205-117-62 **LEADER®** Allergy Tablets

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Authistamine
12-hour relief Allergy Tablets
Chopteniamine maleate
Antihistamine
12-hour relief
(13.1)=: Allergy Tablets
Chlaughenitamine maleate **Antihistamine** 12-hour relief COATING FREE AREA For Allergy Relief Sneezing • Itchy, Watery Eyes • Itchy Throat • Runny Nose 5 8 24 TABLETS, 12 mg each All **Leader®** Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund. 6151/00 0 96295 12021 9

www.myleader.com 1-800-200-6313

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017 CIN 4360889

chlorpheniramine maleate tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:37205-117
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHLORPHENIRAMINE MALEATE (CHLORPHENIRAMINE)	CHLORPHENIRAMINE MALEATE	12 mg	

Inactive Ingredients	
Ingredient Name	Strength
CALCIUM SULFATE	
CARNAUBA WAX	
SILICON DIO XIDE	
SUCROSE	
D&C YELLOW NO. 10	
FD&C BLUE NO. 2	
GELATIN	
HYDROXYPROPYL CELLULOSE	
LACTOSE MONOHYDRATE	
MAGNESIUM STEARATE	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A	
METHYLPARABEN	
CELLULO SE, MICRO CRYSTALLINE	
POLYSORBATE 80	
PO VIDO NE	
PROPYLENE GLYCOL	
SO DIUM BENZO ATE	
SO DIUM LAURETH SULFATE	
TITANIUM DIO XIDE	
TRIETHYL CITRATE	
FD&C YELLOW NO.6	
TALC	

Product Characteristics			
Color	BROWN	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	Allergy;12
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-117-62	24 in 1 CARTON		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040829	12/20/2010	

Labeler - Cardinal Health, Inc. (097537435)

Registrant - KVK-Tech, Inc. (173360061)

Establishment				
Name	Address	ID/FEI	Business Operations	
KVK-Tech, Inc.		173360061	MANUFACTURE(37205-117)	

Revised: 8/2012 Cardinal Health, Inc.