

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

Cardinal Health, Inc.

Unknown Title

Chlorpheniramine maleate 12 mg

Antihistamine

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

alcohol, 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

chlorpheniramine maleate tablet, film coated, extended release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:37205-117 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------------|--------------------------|----------|
| CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 12 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------------------------------------------------|----------|
| CALCIUM SULFATE (UNII: WAT0DDB505) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SUCROSE (UNII: C151H8M554) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| GELATIN (UNII: 2G86QN327L) | |
| HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| POVIDONE (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| TALC (UNII: 7SEV7J4R1U) | |

Product Characteristics

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

Packaging

| # | 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.