

**CHLORPHEN-12- chlorpheniramine maleate tablet, film coated, extended release
KVK-Tech, Inc.**

Chlorphen-12 (Chlorpheniramine Maleate) Extended-Release Tablets, 12 mg

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



Principal Display Panel - 24 Tablets Carton

New Look. Same Trusted Ingredient. MADE IN USA

NDC 10702-017-24

Chlorphen-12

Allergy

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

3 in 1

Fast Acting

Long Lasting

Less Drowsy

24 Tablets

Indoor & Outdoor Allergies

12-hour Extended-Release Tablets

Chlorpheniramine Maleate 12 mg/Antihistamine

SAFETY SEALED:
DO NOT USE IF BACKING IMPRINTED
WITH Chlorpheniramine Maleate
Extended-Release Tablets, 12 mg
IS TORN OR MISSING

**THIS PACKAGING IS NOT
CHILD RESISTANT**

Chlorphen-12[®] Allergy

CHLORPHENIRAMINE MALEATE
EXTENDED-RELEASE TABLETS, 12 mg

[†]When compared to Benadryl^{®††}

^{††}Benadryl[®] is a registered trademark
of Johnson & Johnson

New Look. Same Trusted Ingredient.
NDC 10702-017-24

MADE IN USA

Chlorphen-12[®] Allergy

Chlorphen-12[®]
Allergy
CHLORPHENIRAMINE MALEATE
EXTENDED-RELEASE TABLETS, 12 MG



Chlorphen-12[®]
Allergy
CHLORPHENIRAMINE MALEATE
EXTENDED-RELEASE TABLETS, 12 MG

3in1
Fast Acting
Long Lasting
Less Drowsy[†]

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

3in1 / Fast Acting
Long Lasting
Less Drowsy[†]



24 Tablets

Indoor & Outdoor Allergies
12-hour Extended-Release Tablets
Chlorpheniramine Maleate 12 mg/Antihistamine

NDC 10702-017-24
Lot No: **COATING**
Exp. Date: **FREE AREA**



Chlorphen-12[®] Allergy

CHLORPHENIRAMINE MALEATE
EXTENDED-RELEASE TABLETS, 12 mg



6023/10



31
DESIGN
CODE

Chlorphen-12[®] Allergy

CHLORPHENIRAMINE MALEATE
EXTENDED-RELEASE TABLETS, 12 mg



Drug Facts

Active ingredient (in each tablet) **Purpose**
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 ▶

Drug Facts (continued)

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

Chlorphen-12[®] is manufactured by KVK Tech, Inc.
MADE IN USA

Principal Display panel - 60 Tablets Container Label

New Look. Same Trusted Ingredient. MADE IN USA
NDC 10702-017-06

Chlorphen-12 Allergy

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

3 in 1
Fast Acting
Long Lasting
Less Drowsy

60 Tablets

Indoor & Outdoor Allergies
12-hour Extended-Release Tablets
Chlorpheniramine Maleate 12 mg/Antihistamine



New Look. Same Trusted Ingredient. MADE IN USA
NDC 10702-017-01

Chlorphen-12 Allergy

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

3 in 1
Fast Acting
Long Lasting
Less Drowsy

100 Tablets

Indoor & Outdoor Allergies
12-hour Extended-Release Tablets
Chlorpheniramine Maleate 12 mg/Antihistamine



Principal Display Panel - 4 Tablets in a sachet and a carton of 50 sachets

New Look. Same Trusted Ingredient. MADE IN USA

NDC 10702-017-04

NDC 10702-017-54

Chlorphen-12

Allergy

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat

3 in 1

Fast Acting

Long Lasting

Less Drowsy

4 Tablets in a sachet and a carton of 50 sachets

Indoor & Outdoor Allergies

12-hour Extended-Release Tablets

Chlorpheniramine Maleate 12 mg/Antihistamine



CHLORPHEN-12

chlorpheniramine maleate tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10702-017
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)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
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	orange	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	Chlorphen;12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10702-017-06	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2010	
2	NDC:10702-017-24	24 in 1 CARTON; Type 0: Not a Combination Product	06/15/2010	
3	NDC:10702-017-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2010	
4	NDC:10702-017-54	50 in 1 CARTON	11/29/2018	
4	NDC:10702-017-04	4 in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA040829	06/15/2010	
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Labeler - KVK-Tech, Inc. (173360061)

Registrant - Avanathi, Inc. (832316694)

Establishment

Name	Address	ID/FEI	Business Operations
KVK-Tech, Inc.		173360061	manufacture(10702-017)

Revised: 12/2018

KVK-Tech, Inc.