

**DEXBROMPHERNIRAMINE MALEATE AND PSEUDOEPHEDRINE  
SULFATE 6MG/120MG- dexbrompheniramine maleate and pseudoephedrine sulfate tablet,  
extended release  
KVK-TECH, INC.**

-----

**Dexbrompheniramine maleate 6 mg  
Pseudoephedrine Sulfate 120 mg**

**DRUG FACTS**

**ACTIVE INGREDIENT (IN EACH TABLET)**

Dexbrompheniramine maleate 6 mg

Pseudoephedrine Sulfate 120 mg

**PURPOSE**

Antihistamine

Nasal decongestant

**USES**

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies, and associated with sinusitis
- helps decongest sinus openings and sinus passages
- reduces swelling of nasal passages, shrinks swollen membranes, and temporarily restores freer breathing through the nose
- temporarily alleviates the following symptoms due to hay fever (allergic rhinitis):
  - runny nose
  - sneezing
  - itching of the nose or throat
  - itchy and watery eyes

**WARNINGS**

**Do not use** If you are now taking a prescription monoamineoxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**ASK A DOCTOR BEFORE USE IF YOU HAVE**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

**ASK DOCTOR/PHARMACIST BEFORE USE IF YOU ARE**

- taking sedative or tranquilizers

#### **WHEN USING THIS PRODUCT**

- **do not use more than directed**
- 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

#### **STOP USE AND ASK A DOCTOR IF**

- nervousness, dizziness or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever

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 69 mg and sodium 0 mg
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

#### **INACTIVE INGREDIENTS**

calcium sulfate, carnauba wax, colloidal silicon dioxide, D&C yellow No. 10 aluminum lake, FD&C blue No. 1 aluminum lake, FD&C yellow No. 6 aluminum lake, gelatin, hypromellose, lactose monohydrate, magnesium stearate, methacrylic acid copolymer, methyl parahydroxybenzoate, microcrystalline cellulose, pharmaceutical ink, polysorbate 80, povidone, pregelatinized maize starch, propyl parahydroxy benzoate, sodium benzoate, sodium lauryl sulfate, sucrose, talc, titanium dioxide, triethyl citrate

#### **QUESTIONS**

call 1-215-579-1842

#### **PRODUCT PACKAGING**

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

**Dexbrompheniramine Maleate 6 mg  
and Pseudoephedrine Sulfate 120 mg**

## **Extended-release Tablets**

Antihistamine/Nasal Decongestant

### **COLD & ALLERGY**

Maximum Strength

- Nasal & Sinus Congestion
- Runny Nose, Sneezing
- Itchy, Watery Eyes

12 Hour Sustained Relief

20 EXTENDED-RELEASE TABLETS

SAFETY SEALED: DO NOT USE IF BACKING ON BLISTER CARD IMPRINTED WITH  
DEXBROMPHENIRAMINE MALEATE 6 mg AND PSEUDOEPHEDRINE SULFATE 120 mg IS  
TORN OR MISSING.

Manufactured by KVK-TECH, INC.

Newtown, PA18940 MADE IN USA

## **Principal Display Panel**

### **Carton Label**

**Dexbrompheniramine Maleate 6 mg  
and Pseudoephedrine Sulfate 120 mg  
Extended-release Tablets**

**Antihistamine/Nasal Decongestant**

### **COLD & ALLERGY**

*Maximum Strength*

- **Nasal & Sinus Congestion**
- **Runny Nose, Sneezing**
- **Itchy, Watery Eyes** 12 Hour Sustained Relief

20 EXTENDED-RELEASE TABLETS



**Container Label**

**NDC 10702-005-03**

**Dexbrompheniramine Maleate 6 mg  
and Pseudoephedrine Sulfate 120 mg  
Extended-release Tablets**

**Antihistamine/Nasal Decongestant**

**COLD & ALLERGY**

**Maximum Strength**

- Nasal & Sinus Congestion
- Runny Nose, Sneezing



## Inactive Ingredients

Ingredient Name	Strength
CALCIUM SULFATE (UNII: WAT0DDB505)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

## Product Characteristics

Color	GREEN	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	K;5
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10702-005-21	2 in 1 CARTON	12/17/2018	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:10702-005-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078648	12/17/2018	

Labeler - KVK-TECH, INC. (173360061)

**Registrant** - AVANTHI(832316694)

**Establishment**

Name	Address	ID/FEI	Business Operations
KVK-TECH, INC		173360061	MANUFACTURE(10702-005)

Revised: 12/2017

KVK-TECH, INC.