

Deadened Adhesive Area

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
- Itchy, Watery Eyes

30 EXTENDED-RELEASED TABLETS



DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

Drug Facts	
Active ingredients (in each tablet)	Purpose
Dexbrompheniramine maleate 6 mg	Antihistamine
Pseudoephedrine sulfate 120 mg	Nasal decongestant
Uses	
<ul style="list-style-type: none"> ■ 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 systems due to hay fever (allergic rhinitis): <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ itching of the nose or throat ■ itchy and watery eyes 	
Mfd. by: KVK-TECH, INC. NEWTOWN, PA 18940 MADE IN USA	
	
LOT NO: EXP. DATE:	

6191/02

PEEL HERE FOR MORE DRUG FACTS.

Drug Facts (continued)

Warnings

Do not use if you are now taking a prescription monoamine oxidase 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 a doctor or pharmacist before use if you are taking sedatives 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

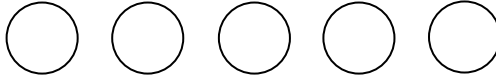
- **each tablet contains:** calcium 69 mg and sodium 0 mg
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

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.

STOP PEELING

IF BACKING HAS BEEN TORN, DO NOT USE. PUSH TABLET THROUGH BACKING.
Contains FD&C Yellow No. 6.



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and Pseudoephedrine Sulfate 120 mg**

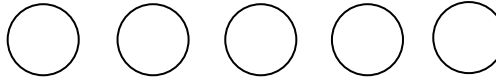
Extended-release Tablets

Antihistamine/ Nasal Decongestant

COLD & ALLERGY

Manufactured By:
KVK-TECH, INC.
Newtown, PA 18940 USA
MADE IN USA

LOT:
EXP:
6126/02



Call your doctor for medical advice about side effects.
You may report side effects to FDA at 1-800-FDA-1088.

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/s/

ROBERT L WEST

02/27/2013

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.