BENZEDREX 09-19-2014- propylhexedrine inhalant BF ASCHER AND CO INC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Benzedrex

Active ingredient..... Purpose

Propylhexedrine 250 mg......Nasal decongestant

Uses

For the temporarily relief of nasal congestion due to a cold, hay fever, or other upper respiratory allergies (allergic rhinitis).

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Temporarily relieves nasal congestion due to a cold, hay fever, or other upper respiratory allergies (allergic rhinitis).

Warnings

- Do not exceed recommended dosage.
- This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge.
- The use of this container by more than one person may spread infection.
- Use only as directed.
- Frequent or prolonged use may cause nasal congestion to recur or worsen.
- Ill effects may result if taken internally

Do not use this product for more than three days.

Stop use and consult a doctor if symptoms persist.

If pregnant or breast-feeding, ask a health professional before use.

Keep this and all drugs out of reach of children. In case of overdose or ingestion of contents, get medical help or contact a poison control center immediately.

Directions

- adults and children 6 to 12 years of age (with adult supervision): two inhalations in each nostril not more than every two hours.
- children under 6 years of age: consult a doctor

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Other information

- store at 59°-86° F (15°-30° C)
- keep inhaler tightly closed
- mfd. in USA for B.F. Ascher & Co., Inc.
- this inhaler is effective for a minimum of 3 months after first use

Inactive ingredients

lavender oil, menthol

Questions?

Call 1-800-324-1880, 7:30am - 4:00pm Central, Mon. - Fri., or visit us at www.bfascher.com



BENZEDREX 09-19-2014

propylhexedrine inhalant

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0225-0610			
Route of Administration	NASAL					
Noute of Administration	17.07.12					

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength Strength

PROPYLHEXEDRINE (UNII: LQU92IU8LL) (PROPYLHEXEDRINE - UNII:LQU92IU8LL)

PROPYLHEXEDRINE

250 mg

Inactive Ingredients

Strength
Strength

LAVENDER OIL (UNII: ZBP1YXW0H8)

MENTHOL (UNII: L7T10EIP3A)

Packaging

- 1				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:0225- 0610-23	1 in 1 INHALER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	09/19/2014	02/28/2025

Marketing Information

9				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M012	09/19/2014	02/28/2025	

Labeler - BF ASCHER AND CO INC (003854403)

Revised: 7/2023 BF ASCHER AND CO INC