BREAZE NASAL SINUS COLDS AND ALLERGIES- oxymetazoline hydrochloride spray
Samson Pharmaceuticals, 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.

Breaze® Nasal
Sinus Colds and Allergies

DRUG FACT

ACTIVE INGREDIENT

Oxymetazoline hydrochloride, 0.05%

PURPOSE

Nasal Decongestant

Uses

- Temporarily relieves nasal congestion due to:
  - Common cold. Hay fever. Sinusitis
  - Upper respiratory allergies
  - Shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have

- **High blood pressure**
- **Heart disease**
- **Diabetes**
- **Thyroid diseases**
- **Trouble urinating due to enlarged prostate gland**

When using this product

Do not use more than directed

- Do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- Temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may occur
- Use of this container by more than one person may spread infection

Stop use and ask a doctor if symptoms persist

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adult & children 6 to under 12 years of age (with adult supervision): 2 to 3 sprays in age nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24 –hr period.

Children under 6 years of age: ask a doctor. To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

Other information

- Store between 20C to 25C (68 to 77F).
- Retain carton for future reference on full labeling.

Inactive Ingredients

Benzalkonium Chloride, Eucalyptus Globulus (Eucaplyptus) Leaf Oil, Camphor, Menthol, Editate Disodium, Sodium Phosphate Dibasic, Polysorbate 80, Sodium Phosphate Monobasic, Propylene Glycol, Water (Aqua).

Question or Comments?

1-888-995-9935

Manufactured by:
Samson Pharmaceutical
Commerce, CA 90040
Made in USA

Visit our website at
www.samson.pharmaceutical.com
Made in USA

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

Breaze®

MADE IN THE U.S.A.
WITH PRIDE

Relieves Congestion

Nasal
Spray

Sinus
Colds & Allergies

12 Hour Relief

- ***Oxymetazoline HCl Nasal Solution***
- ***Nasal Decongestant***

1 FL OZ (30 mL)

BREAZE NASAL SINUS COLDS AND ALLERGIES

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:20146-4006
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Oxymetazoline hydrochloride (UNII: K89MJ0S5VY) (Oxymetazoline - UNII:8VLN5B44ZY)	Oxymetazoline hydrochloride	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7)	
Eucalyptus Oil (UNII: 2R04ONI662)	
Menthol, Unspecified Form (UNII: L7T10EIP3A)	
Edetate Disodium (UNII: 7FLD91C86K)	
Sodium Phosphate, Dibasic, Anhydrous (UNII: 22ADO53M6F)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Sodium Phosphate, Monobasic, Anhydrous (UNII: KH7I04HPUU)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20146-4006-1	1 in 1 CARTON	01/01/2015	
1		30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	01/01/2015	

Labeler - Samson Pharmaceuticals, Inc. (088169581)

Establishment

Name	Address	ID/FEI	Business Operations
Samson Pharmaceuticals, Inc.		088169581	MANUFACTURE(20146-4006)