

BREAZE NASAL SINUS COLDS AND ALLERGIES- oxymetazoline hydrochloride spray
Samsom 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 each 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 (Eucalyptus) 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)



DO NOT USE IF PROTECTIVE SEAL OVER
CAP IS TORN OR MISSING

Drug Facts

| Active Ingredient | Purpose |
|------------------------------------|--------------------|
| Oxymetazoline hydrochloride, 0.05% | 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

- Heart disease • High blood pressure
- Diabetes • Thyroid disease
- Trouble urinating due to an enlarged prostate gland

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Drug Facts

(continued)

Other information

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

Inactive Ingredients

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

Keep carton for future reference on full labeling.

Relieves Congestion

Nasal Spray
Sinus

Breaze



Relieves Congestion

Nasal Spray

Sinus

Colds & Allergies

12 Hour Relief

• Oxymetazoline HCl Nasal Solution

• Nasal Decongestant

1 FL OZ (30 mL)

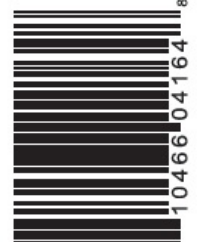
Relieves Congestion

Nasal Spray
Sinus

12 Hour Relief

Manufactured by:
Samson Pharmaceuticals, Inc.
Commerce, CA 90040 USA

www.samsonpharmaceutical.com
Questions or Comments?
1-888-995-9935



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: 2R040NI662) | |
| Menthol, Unspecified Form (UNII: L7T10EIP3A) | |
| Edetate Disodium (UNII: 7FLD91C86K) | |
| Sodium Phosphate, Dibasic, Anhydrous (UNII: 22ADO53M6F) | |
| Polysorbate 80 (UNII: 6OZP39ZG8H) | |
| Sodium Phosphate, Monobasic, Anhydrous (UNII: KH7I04HPUJ) | |
| 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 | | |
| 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) |