

MAXIMUM STRENGTH NASAL DECONGESTANT- oxymetazoline spray liquid

CVS Health

Drug Facts

Active Ingredient

Oxymetazoline Hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- Shrinks swollen 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 enlarged prostate gland.

When using this product

- **Do not use more than directed**
- do not use for more than three 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 the reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Before using for the first time, remove the protective cap from the tip and prime the pump by depressing pump firmly several times. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress rim with a firm and even stroke, and sniff deeply.
- Wipe nozzle clean after use.
- Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- Children under 6 years of age consult a doctor.

Other information

- store between 20° and 25°C (68° to 77°F)
- retain carton for future reference on full labeling

Inactive Ingredients

Benzalkonium Chloride Solution, Benzyl Alcohol, Camphor, Edetate Sodium, Eucalyptol, Glycerin, Menthol, Polysorbate 80, Propylene Glycol, Purified Water, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic

CVS Health Severe Congestion

Maximum Strength

Nasal Spray

Oxymetazoline HCL 0.05%

12 hour Nasal Spray

Net Wt 0.5 FLOZ (15ml)

SEVERE
CVS Health.
Nasal Spray
OXYMETAZOLINE HCl 0.05%
Nasal decongestant
12 HOUR NASAL SPRAY

DO NOT USE IF PRINTED 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 • upper respiratory allergies • temporarily relieves sinus congestion and pressure • shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have • heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to an 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 (1-800-222-1222) right away.

Directions

Cap removal instructions: Push firmly down on cap and turn counter clockwise to remove. To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use. To reapply cap turn cap on bottle clockwise until secure.
• adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
• children under 6 years of age: ask a doctor.

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 Solution, Benzyl Alcohol, Camphor, Edetate Sodium, Eucalyptol, Glycerin, Menthol, Polysorbate 80, Propylene Glycol, Purified Water, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic

IMPORTANT: KEEP OUTER CARTON FOR FUTURE REFERENCE ON FULL LABELING.

*This product is not manufactured or distributed by Bayer HealthCare LLC, the distributor of Afrin® Severe Congestion Nasal Spray.

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Woonsocket, RI 02895
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CVS.com®
1-800-SHOP CVS
Made in the U.S.A. of U.S. and imported ingredients and components.
V-34744

100% money back guaranteed.
CVS.com/returnpolicy



Compare to the active ingredient in Afrin® Severe Congestion Nasal Spray*

Severe

NDC 69842-316-51

SEVERE
Nasal Spray



OXYMETAZOLINE HCl 0.05%
Nasal decongestant

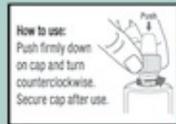
12 HOUR NASAL SPRAY

- Relieves nasal congestion & sinus congestion/pressure
- Plus Menthol



Actual Bottle Size on Side Panel

0.5 FL OZ (15 mL)



How to use:
Push firmly down on cap and turn counterclockwise. Secure cap after use.

Actual Size Package Contains One Bottle

LOT

EXP

#487164



0 50428 08744 2

5031327

CVS
Health.

Severe

SEVERE

NDC 69842-316-51

Nasal
Spray



OXYMETAZOLINE
HCl 0.05%
Nasal decongestant

0.5 FL OZ (15 mL)

7908079

**DO NOT USE IF PRINTED SEAL OVER
CAP IS TORN OR MISSING.**

SEE CARTON FOR FULL LABELING

Active ingredient: Oxymetazoline hydrochloride 0.05%

Uses: See carton. **Warnings:** Ask a doctor before use if you

have • heart disease • high blood pressure • thyroid disease

• diabetes • trouble urinating due to an 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 (1-800-222-1222) right away.

Directions: • adults and children 6 to under 12 years of age

(with adult supervision): 2 or 3 sprays in each nostril not more

often than every 10 to 12 hours. Do not exceed 2 doses in any

24-hour period. • children under 6 years of age: ask a doctor.

• store between 20° to 25°C (68° to 77°F)

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1-800-SHOP CVS V-34744

7908089

MAXIMUM STRENGTH NASAL DECONGESTANT

oxymetazoline spray liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69842-316 |
| Route of Administration | NASAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|--------------------|
| OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY) | OXYMETAZOLINE HYDROCHLORIDE | 50 mg in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW) | |
| SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |

| | |
|---|--|
| WATER (UNII: 059QF0KO0R) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) | |
| EUCALYPTOL (UNII: RV6J6604TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69842-316-51 | 1 in 1 CARTON | 08/30/2018 | |
| 1 | | 15 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 Drug | M012 | 08/30/2018 | |

Labeler - CVS Health (062312574)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|--|
| Sheffield Pharmaceutical LLC | | 151177797 | manufacture(69842-316) , analysis(69842-316) |

Revised: 5/2024

CVS Health