

MAXIMUM STRENGTH NASAL DECONGESTANT- oxymetazoline spray liquid

CVS Health

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.

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

Principal Panel 0.5 FLOZ Bottle

 **CVS**
Health.

Severe Congestion

**MAXIMUM
STRENGTH**

**Nasal
Spray**



OXYMETAZOLINE HCl 0.05%
Nasal decongestant

12 HOUR NASAL SPRAY

- Fast, powerful congestion relief
- For colds & allergies

0.5 FL OZ (15 mL)

7908078

Front Label

CVS Health Severe Congestion

Maximum Strength

Nasal Spray

Oxymetazoline HCL 0.05%

12 hour Nasal Spray

Net Wt 0.5 FLOZ (15ml)

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0.5 FL OZ (15 mL)

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Front Label

Principal display panel- Bottle back label

SEE CARTON FOR FULL LABELING.

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 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.

Active ingredient Oxymetazoline hydrochloride 0.05%

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

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Woonsocket, RI 02895 © 2018 CVS/pharmacy V-34744

7908088

Rear Label

SEE CARTON FOR FULL LABELING.

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 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.

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Rear Label

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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 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. **Active ingredient** Oxymetazoline hydrochloride 0.05% • store between 20° to 25°C (68° to 77°F) **Distributed by: CVS Pharmacy, Inc.** One CVS Drive, Woonsocket, RI 02895 © 2018 CVS/pharmacy V-34744

7908088

Rear Label

Principal display panel -Carton

CVS Health Severe Congestion

Maximum Strength

Nasal Spray

Oxymetazoline HCL 0.05%

12 hour Nasal Spray

Net Wt 0.5 FLOZ (15ml)

Severe Congestion
CVS Health.
Nasal Spray
MAXIMUM STRENGTH
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
 infections • temporarily relieves sinus congestion and
 pressure • softens 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 right away.

Directions
 Cap removal instructions: Push firmly down on cap and
 turn counterclockwise 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 17 years of age (with
 adult supervision): 2 or 3 sprays in each nostril not
 more often than every 12 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)
 • See carton for future
 reference on full labeling

Inactive ingredients
 Benzalkonium Chloride Solution,
 Ethanol Alcohol, Glycerin,
 Hydroxyethylcellulose, Hydroxypropylcellulose,
 Hydroxypropylmethylcellulose, Hydroxypropyltrimethylammonium
 chloride, Methylparaben, Propylparaben, Sodium Chloride,
 Sodium Phosphate Dibasic, Sodium Phosphate
 Monobasic

Cap removal instructions:
 Push firmly down on cap
 and turn counterclockwise
 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.

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

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

CVS Health. Compare to the active
 ingredient in Afrin® Severe
 Congestion Nasal Spray™
Severe Congestion

**MAXIMUM
 STRENGTH**
Nasal Spray **12 HOUR**

**OXYMETAZOLINE
 HCl 0.05%**
Nasal decongestant
12 HOUR NASAL SPRAY
 • Fast, powerful congestion relief
 • For colds & allergies



Actual Bottle Size
 on Side Panel
**0.5 FL OZ
 (15 mL)**

Distributed by:
 CVS Pharmacy, Inc.,
 One CVS Drive,
 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-31714

CVS Quality
 Every Day. Guaranteed.

Package Contains
 One Bottle

Actual Size

LOT
 DP
 #425123

 0 50428 60022 1



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
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POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
WATER (UNII: 059QF0KO0R)	
MENTHOL (UNII: L7T10EP3A)	
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 final	part341	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)