

## **NO DRIP SEVERE NASAL MIST- 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.*

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### **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, Camphor, Cellulose Gum, Disodium EDTA, Disodium Phosphate, Eucalyptol, Glycerin, Menthol, Microcrystalline Cellulose and Carboxymethylcellulose Sodium, PEG-6, Povidone, Propylene Glycol, Sodium Phosphate, Water (purified)

## Principal Panel 0.5 FLOZ Bottle

**CVS Health.** **Severe**

**No Drip**  
**Nasal Mist**  
OXYMETAZOLINE  
HCl 0.05%  
Nasal decongestant  
0.5 FL OZ (15 mL)

**12 HOUR**

SEE CARTON FOR FULL LABELING  
DO NOT USE IF PRINTED SEAL OVER  
CAP IS TORN OR MISSING

**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 right away. **Directions** To use: squeeze cap at base on opposite sides and twist cap counterclockwise to remove. Secure cap after use. • 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.

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# CVS Health No Drip Severe Nasal Mist

Nasal Spray

Oxymetazoline HCL 0.05%

12 hour Nasal Spray

Net Wt 0.5 FLOZ (15ml)



Severe

No Drip

## Nasal Mist

OXYMETAZOLINE

HCl 0.05%

Nasal decongestant

0.5 FL OZ (15 mL)



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Severe

No Drip

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HCl 0.05%

Nasal decongestant

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Severe

No Drip

## Nasal Mist

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**CVS Health.**

**No Drip**

# Nasal Mist

OXYMETAZOLINE HCl 0.05%  
Nasal decongestant

**12 HOUR**

**Severe**

**SEE CARTON FOR FULL LABELING  
DO NOT USE IF PRINTED SEAL OVER  
CAP IS TORN OR MISSING**

**Active Ingredient**  
Oxymetazoline hydrochloride 0.05%

**Uses** • See Carton.

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Principal display panel- Carton label

**CVS Health.**

**No Drip**

# Nasal Mist

OXYMETAZOLINE HCl 0.05%  
Nasal decongestant

**12 HOUR**

**Severe**

**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 right away

**Directions**  
Before using the first time, remove the protective clip from the tip and prime pump by depressing pump briefly several times. To spray, hold bottle with thumb at base and middle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress rim with a firm, 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 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

**Other information**  
• store between 20° to 25°C (68° to 77°F)  
• retain carton for future reference on full labeling

**Inactive ingredients**  
Benzalkonium Chloride, Camphor, Cellulose Gum, Docusone EDTA, Docusone Phosphate, Fucalysol, Glycerin, Menthol, Monocrystatine, Cellulose and Carbomethylcellulose Sodium, PEG-6, Povidone, Propylene Glycol, Sodium Phosphate, Water (purified)

**Cap removal instructions:**  
To remove cap, squeeze cap at base on opposite sides on the two turn impressions with fingers. While squeezing, twist cap counterclockwise to remove. Press down to use. Refer to arrows on cap.

**To reapply cap, turn cap on pump clockwise until it locks.**

**This product is not manufactured or distributed by Bayer HealthCare LLC, the distributor of Atrine® No Drip Severe Congestion Pump Mist.**

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

**CVS Health.**

Compare to the active ingredient in Atrine® No Drip Severe Congestion Pump Mist

**No Drip**

# Nasal Mist

OXYMETAZOLINE HCl 0.05%  
Nasal decongestant

**12 HOUR**

**12 HOUR PUMP MIST**

- Won't drip from nose or down throat
- Fast, powerful congestion relief
- Colds; allergies

**Actual Bottle Size on Side Panel**

**0.5 FL OZ (15 mL)**

**Actual Size**

**Package Contains One Bottle**

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**CVS Quality**  
Member Since 1969

LOT  
EXP  
502194

858828 0-50429-30053-4

No Drip  
Nasal Mist  
12 HOUR PUMP MIST



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

**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 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  
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• 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**  
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**Directions**  
Before using the first time, remove the protective cap from the tip and prime pump by depressing pump firmly several times. To spray, hold bottle with thumb at base and index between first and second fingers. Without tilting head, insert nozzle into nostril. If you depress rim with a firm, even stroke and sniff deeply, wipe nozzle clean after use.  
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**Drug Facts** (continued)

**Other information**  
• store between 20° to 25°C (68° to 77°F)  
• retain carton for future reference or full labeling

**Inactive ingredients**  
Benzalkonium Chloride, Camphor, Cellulose Gum, Croscarmellose Sodium, EDTA, Glycerin, Menthol, Methylparaben, Propylparaben, Purified Water, Sodium Phosphate, Water (purified)

**Cap removal instructions:**  
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**This product is not manufactured or distributed by Bayer HealthCare LLC, the distributor of Afrin® No Drip Severe Congestion Pump Mist.**

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



Compare to the active ingredient in Afrin® No Drip Severe Congestion Pump Mist\*  
**Severe**

No Drip  
Nasal Mist

12 HOUR

OXYMETAZOLINE HCl 0.05%  
Nasal decongestant  
12 HOUR PUMP MIST

- Won't drip from nose or down throat
- Fast, powerful congestion relief
- Colds; allergies



Actual Bottle Size on Side Panel

0.5 FL OZ (15 mL)



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Package Contains One Bottle

Actual Size

LOT  
EXP  
#R558028  
50428 30053  
858828 0-00428-30053-4

502194



CVS Health No Drip

**Severe Nasal Mist**

Nasal Spray

**Oxymetazoline HCL 0.05%**

**12 hour Nasal Spray**

Net Wt 0.5 FLOZ (15ml)

No Drip  
Nasal Mist  
12 HOUR PUMP MIST



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

**Drug Facts**

**Active ingredient** Oxymetazoline hydrochloride 0.05%. **Purpose** Nasal decongestant

**Uses** • temporarily relieves nasal congestion due to:  
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• 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 or full labeling

**Inactive ingredients**  
Benzalkonium Chloride, Camphor, Cellulose Gum, Croscollon (EFTA), Croscollon Phosphate, (sucralose), Glycerin, Menthol, Moxycycline, Cellulose and Carbomethylcellulose Sodium, PEG-6, Polidone, Propylene Glycol, Sodium Phosphate, Water (purified)

**Cap removal instructions:**  
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To reapply cap, turn cap on pump clockwise until it locks.

**This product is not manufactured or distributed by Bayer HealthCare LLC, the distributor of Afrin® No Drip Severe Congestion Pump Mist.**

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



Compare to the active ingredient in Afrin® No Drip Severe Congestion Pump Mist\*  
**Severe**

No Drip  
Nasal Mist

12 HOUR

OXYMETAZOLINE HCl 0.05%  
Nasal decongestant  
12 HOUR PUMP MIST

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- Colds; allergies



Actual Bottle Size on Side Panel

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Package Contains One Bottle

Actual Size

LOT  
EXP  
#R558028  
50428 30053  
858828 0-00429-30053-4

502194



## NO DRIP SEVERE NASAL MIST

oxymetazoline spray liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-315
<b>Route of Administration</b>	NASAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength



<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>POLYETHYLENE GLYCOL 300</b> (UNII: 5655G9Y8AQ)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>SODIUM PHOSPHATE, MONOBASIC</b> (UNII: 3980JIH2SW)
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>POVIDONE</b> (UNII: FZ989GH94E)
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)
<b>MENTHOL</b> (UNII: L7T10EIP3A)
<b>EUCALYPTOL</b> (UNII: RV6J6604TK)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-315-51	1 in 1 CARTON	08/30/2018	
1		15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:69842-315-30	1 in 1 CARTON	04/30/2022	
2		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	08/30/2018	

**Labeler** - CVS Health (062312574)

**Registrant** - Sheffield Pharmaceuticals LLC (151177797)

### Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceutical LLC		151177797	manufacture(69842-315)