

# **MAJOR NASAL DECONGESTANT- oxymetazoline hydrochloride spray**

## **Major Pharmaceuticals**

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### **Major Nasal Decongestant Spray**

#### **Drug Fact**

##### **Active Ingredient**

Oxymetazoline HCL 0.05%

##### **Purpose**

Nasal Decongestant

##### **Uses**

##### **Temporarily relieves nasal congestion due to:**

- common cold
- hay fever
- sinusitis
- upper respiratory allergies
- 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

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**

- 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. To spray, squeeze bottle quickly and firmly. Do not tilt head backwards while spraying, wipe nozzle clean after use.

### **Other information**

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

### **Inactive ingredients**

benzalkonium chloride, edetate disodium, glycerin, polyethylene glycol, povidone, propylene glycol, sodium phosphate dibasic, sodium phosphate monobasic, water

### **Principal Display Panel**

Major© Original Nasal Spray NDC 0904-7435-35  
Oxymetazoline Hydrochloride 0.05%  
12 hour Nasal Mist Nasal Decongestant  
1/2 FLOZ (15ML)

NDC 0904-7435-35

**MAJOR<sup>®</sup>**

**Nasal  
Decongestant Spray**

*Oxymetazoline HCl 0.05%*

***Original***

***Fast, Powerful  
Congestion Relief***

*For Colds & Allergies  
Up to 12 Hour Relief*

***Maximum Strength***

***1/2 FL OZ (15 mL)***

760100

Nasal Decongestant Spray  
Oxymetazoline HCl 0.05%

MAJOR®

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  
• 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, Disodium EDTA, Disodium Phosphate, Glycerin, PEG-6, Propylene Glycol, PVP, Sodium Phosphate, Water (Purified)

Questions? Call 1-800-222-1807

IMPORTANT: KEEP OUTER CARTON FOR FUTURE REFERENCE ON FULL LABELING

This product starts to work in seconds providing up to 12 hours of nasal congestion relief without drowsiness.

Up to 12-hour relief from nasal congestion. Relief lasts All-Day or All-Night.

Distributed by:  
MAJOR® PHARMACEUTICALS  
Indianapolis, IN 46268  
Questions or comments?  
Call (800) 616-2471  
www.majorpharmaceuticals.com

\*This product is not manufactured or distributed by ©Bayer HealthCare LLC, owner of the registered trademark Afrin® Original Nasal Spray.

MADE IN THE U.S.A. OF U.S. AND IMPORTED INGREDIENTS AND COMPONENTS

Rev. 10/23 M-101 Re-order No. 701387

560100

NDC 0904-7435-35

Compare to the active ingredient in Afrin® Original Nasal Spray\*

MAJOR®

## Nasal Decongestant Spray

Oxymetazoline HCl 0.05%

Original

Fast, Powerful  
Congestion  
Relief

For Colds & Allergies  
Up to 12 Hour Relief



Maximum  
Strength

1/2 FL OZ (15 mL)



How to use:

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

ACTUAL SIZE

LOT

EXP



**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)

Rev.10/23 M-101 Re-order No. 701387



760101

## MAJOR NASAL DECONGESTANT

oxymetazoline hydrochloride spray

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0904-7435 |
| <b>Route of Administration</b> | NASAL          |                           |               |

### Active Ingredient/Active Moiety

| <b>Ingredient Name</b>   | <b>Basis of Strength</b>    | <b>Strength</b>   |
|--|-----------------------------|-------------------|
| <b>OXYMETAZOLINE HYDROCHLORIDE</b> (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII: 8VLN5B44ZY) | OXYMETAZOLINE HYDROCHLORIDE | 0.5 mg<br>in 1 mL |

### Inactive Ingredients

| <b>Ingredient Name</b>   | <b>Strength</b> |
|--|-----------------|
| <b>POLYETHYLENE GLYCOL 300</b> (UNII: 5655G9Y8AQ)              |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                             |                 |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                     |                 |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)                     |                 |
| <b>SODIUM PHOSPHATE, MONOBASIC</b> (UNII: 3980JIH2SW)          |                 |
| <b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F) |                 |
| <b>POVIDONE</b> (UNII: FZ989GH94E)                             |                 |

**BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7)

**WATER** (UNII: 059QF0KO0R)

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0904-7435-35 | 1 in 1 CARTON   | 12/31/2023           |                    |
| 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                                     | 12/31/2023           |                    |

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 12/2023

Major Pharmaceuticals