# MAJOR- nasal decongestant spray MAJOR PHARMACEUTICALS

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# **MAJOR Original Nasal Decongestant Spray Drug Facts**

### **Active ingredient**

Oxymetazoline hydrochloride 0.05%

# **Purpose**

Nasal Decongestant

### Uses

- temporarily relief of nasal congestion due to the
- common cold
- hay fever
- other 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
- diabetes
- thyroid disease
- 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 at (1-800-222-1222).

### **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

To use: Push firmly down on cap and turn counter clockwise.

**To Spray:** Squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use. Secure cap after use.

### Other information

- store at room temperature
- Keep this carton for future reference on full labeling.

# **Inactive ingredients**

benzalkonium chloride, benzyl alcohol, edetate disodium, polyethylene glycol, povidone, propylene glycol, purified water, sodium phosphate dibasic, sodium phosphate monobasic.

### **Questions or comments?**

1-866-467-2748

# **Principal Display Panel**

**MAJOR®** 

Compare to the active ingredient in Afrin® Original\*

NDC# 0904-7006-35

**Nasal Decongestant Spray** 

**OXYMETAZOLINE HCL 0.05%** 

Original

Fast, Powerful Congestion Relief

For Colds & Allergies

Up to 12 Hour Relief

12 Hour Relief

## **Maximum Strength**

### **NASAL DECONGESTANT**

### **12 HOUR**

1/2 FL OZ (15 mL)

TAMPER-EVIDENT: DO NOT USE IF PRINTED SEAL OVER CAP IS BROKEN OR MISSING.

Distributed by:

# MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive

Suite 233

Livonia, MI 48152

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.

\*This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark Afrin<sup>®</sup> Original.



# **MAJOR**

nasal decongestant spray

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0904-7006 Route of Administration NASAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

| OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) | OXYMETAZ OLINE | 0.05 g    |
|--|----------------|-----------|
| (OXYMETAZ OLINE - UNII:8VLN5B44ZY)             | HYDROCHLORIDE  | in 100 mL |

| Inactive Ingredients   |          |  |  |
|--|----------|--|--|
| Ingredient Name  | Strength |  |  |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)                         |          |  |  |
| BENZYL ALCOHOL (UNII: LKG8494WBH)                                |          |  |  |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                              |          |  |  |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)              |          |  |  |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)                         |          |  |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                              |          |  |  |
| WATER (UNII: 059QF0KO0R)   |          |  |  |
| SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)   |          |  |  |
| SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) |          |  |  |

| P | Packaging            |   |                         |                       |  |  |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| 1 | NDC:0904-<br>7006-35 | 1 in 1 CARTON   | 05/16/2019              |                       |  |  |
| 1 |                      | 15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product |                         |                       |  |  |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug    | M012  | 05/16/2019              |                       |  |
|                       |   |                         |                       |  |

# Labeler - MAJOR PHARMACEUTICALS (191427277)

Revised: 10/2023 MAJOR PHARMACEUTICALS