

AFRIN ORIGINAL- oxymetazoline hydrochloride spray
Bayer HealthCare LLC.

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.

Afrin®

Original

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
- 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.

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 spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

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, edetate disodium, polyethylene glycol, povidone, propylene glycol, purified water, sodium phosphate dibasic, sodium phosphate monobasic

Questions or comments?

Call 1-800-317-2165

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

Afrin®

Oxymetazoline HCl Nasal Solution-Nasal Decongestant

Original

NASAL SPRAY

Fast, Powerful

Congestion

Relief

Colds • Allergies

up to 12

Hour

Relief

Maximum

Strength

#1 Doctor & Pharmacist

Recommended Brand

1/2 FL OZ (15 mL)



AFRIN ORIGINAL

oxymetazoline hydrochloride spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11523-1167 |
| Route of Administration | NASAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|---------------------|
| OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY) | OXYMETAZOLINE HYDROCHLORIDE | 0.05 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) | |
| SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:11523-1167-2 | 2 in 1 CARTON | 07/14/1975 | |
| 1 | | 21 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | | |
| 2 | NDC:11523-1167-3 | 1 in 1 CARTON | 07/14/1975 | |
| 2 | | 20 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | | |
| 3 | NDC:11523-1167-4 | 3 in 1 CARTON | 07/14/1975 | |
| 3 | | 30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | | |
| 4 | NDC:11523-1167-5 | 1 in 1 CARTON | 07/14/1975 | |
| 4 | | 30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | | |
| 5 | NDC:11523-1167-6 | 1 in 1 CARTON | 07/14/1975 | |
| 5 | | 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 |
|---------------------------|---|-----------------------------|---------------------------|
|---------------------------|---|-----------------------------|---------------------------|

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 3/2021

Bayer HealthCare LLC.