

QUALITY CHOICE NASAL- oxymetazoline hydrochloride spray QUALITY CHOICE (CHAIN DRUG MARKETING ASSOCIATION)

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.

Quality Choice Nasal Spray 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 right away (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: Shake well before use. Push down cup while turning counter-clockwise and remove cap. Remove clip under rim. Before using the first time, prime metered pump by depressing pump firmly several times. To spray, hold bottle with thumb at base and nozzle rim 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. Replace clip under rim and secure cap after use.

Other information

- store at room temperature

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

Inactive ingredients

benzalkonium chloride, benzyl alcohol, edetate disodium, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, polyethylene glycol, povidone, purified water, sodium phosphate dibasic, sodium phosphate monobasic, xanthan gum.

Package/Label Principal Display Panel

QUALITY CHOICE®

NDC# **63868-079-01**

***Compare to active ingredient in Afrin® No Drip Extra Moisturizing Pump Mist**

12 Hour Relief

Nasal Mist No Drip

Extra Moisturizing

Oxymetazoline HCl 0.05%

Nasal Solution

Fast, powerful Congestion Relief

For Colds & Allergies

Helps Rehydrate

Dry Nasal Passages

No Drip Pump Mist Won't Drip from Nose or Down Throat

1 FL OZ (30mL)

100% QC SATISFACTION GURANTEED

IMPORTANT: Keep this carton for future reference on full labeling.

How to use:

Push down cup while turning counter-clockwise and remove cap. Remove clip under rim. Secure cap after use.

Distributed by C.D.M.A., Inc. ©

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

Questions: 248-449-9300

*This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Afrin[®] Extra Moisturizing.

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Drug Facts (continued)

Inactive ingredients
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Questions? 1-866-467-2748

*This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Afrin® No Drip Extra Moisturizing Pump Mist.

Distributed by C.D.M.A., Inc.®
45137 W 9 Mile Rd
Novi, MI 48275
www.qualitychoice.com
Questions: 300-935-2362

How to use:
Push down cap while turning counter-clockwise and remove cap. Remove clip under rim. Secure cap after use.

QC QUALITY CHOICE

12 Hour Relief No Drip Nasal Mist

NDC 63868-079-01

QC QUALITY CHOICE

*Compare to the active ingredient in Afrin® No Drip Extra Moisturizing Pump Mist

12 Hour Relief Nasal Mist No Drip

Extra Moisturizing

Oxymetazoline HCl 0.05% Nasal Solution

Fast, Powerful Congestion Relief For Colds & Allergies

Helps Rehydrate Dry Nasal Passages

No Drip Pump Mist Won't Drip from Nose or Down Throat

QC QUALITY CHOICE

12 Hour Relief Nasal Mist No Drip

Extra Moisturizing

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Fast, Powerful Congestion Relief For Colds & Allergies

Helps Rehydrate Dry Nasal Passages

1 FL OZ (30 mL)

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IMPORTANT: Keep this carton for future reference on full labeling.

72030QCFC

LOT:

EXP:

QUALITY CHOICE NASAL

oxymetazoline hydrochloride spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-079 |
| Route of Administration | NASAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------------|--------------------|
| OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY) | OXYMETAZOLINE HYDROCHLORIDE | .05 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) | |
| SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|--|
| Color | WHITE (off white) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63868-079-01 | 1 in 1 CARTON | 04/17/2019 | |
| 1 | | 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 | 04/17/2019 | |

Labeler - QUALITY CHOICE (CHAIN DRUG MARKETING ASSOCIATION) (011920774)