

**OXYMETAZOLINE HYDROCHLORIDE- oxymetazoline hydrochloride spray**  
**CHAIN DRUG MARKETING ASSOCIATION INC.**

*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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**Original Nasal Spray**

**Congestion Relief**

**Active Ingredient**

**Purpose**

Oxymetazoline HCl 0.05%..... Nasal decongestant

Nasal Decongestant

**Uses**

- temporarily relieves nasal congestion due to:
  - common cold
  - hay fever
  - upper respiratory allergies
- shrinks swollen nasal membranes so you can breathe more freely

**Warnings**

**Ask a doctor before use if you have**

- heart disease
- thyroid disease
- high blood pressure
- 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***

- **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 10-12 hours. Do not exceed 2 doses in any 24-hour period.
- **children under 6 years of age:** ask a doctor
- **Shake well before use.**
- to spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

***Other information***

- store between 20°C to 25°C (68°F 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 monobasic, sodium phosphate dibasic

- Tamper Evident: Do not use the product if the temper evident seal is broken or missing.
- This product is not manufactured or distributed by Bayer HealthCare LLC distributor of Afrin Original Nasal Spray.

**Questions or comments?**

1-800-935-2362, (Mon-Fri. 9 am-5 pm EST)

**Distributed by C.D.M.A Inc.**

**43157 W 9 Mile Rd**

**Novi, MI 48375**

**[www.qualitychoice.com](http://www.qualitychoice.com)**

**Question: 800-935-2362**

**PRINCIPAL DISPLAY PANEL**

NDC-63868-**607**-01



## OXYMETAZOLINE HYDROCHLORIDE

oxymetazoline hydrochloride spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-607
<b>Route of Administration</b>	NASAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY)	OXYMETAZOLINE	0.05 g

(OXYMETAZOLINE - UNII:8VLN5B44ZY) HYDROCHLORIDE in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM PHOSPHATE, MONOBASIC</b> (UNII: 3980JIH2SW)	
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-607-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/01/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/01/2021	

**Labeler** - CHAIN DRUG MARKETING ASSOCIATION INC. (011920774)

**Registrant** - Seaway Pharma Inc. (117218785)

### Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma Inc.		117218785	manufacture(63868-607)

Revised: 7/2023

CHAIN DRUG MARKETING ASSOCIATION INC.