

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

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

Question: 800-935-2362

PRINCIPAL DISPLAY PANEL

NDC-63868-**607**-01



OXYMETAZOLINE HYDROCHLORIDE

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-607
Route of Administration	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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM PHOSPHATE, DIBASIC (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 Drug	M012	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: 12/2024

CHAIN DRUG MARKETING ASSOCIATION INC.