OXYMETAZOLINE HYDROCHLORIDE- oxymetazoline hydrochloride solution
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.

No Drip Severe Congestion

Nasal Pump Mist

Active Ingredient **Purpose**

Oxymetazoline HCl 0.05% ..... Nasal decongestant

- Rapid & Powerful Congestion Relief

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

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 open, rotate cap to align the marks. Squeeze cap on both sides and turn in a counter-clockwise direction and pull off to remove. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting the head insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use and snap back onto the bottle.

Other information

- store between 20° -25°C (68°-77 °F)
- retain carton for future reference on full labeling

Questions or comments?
1-800-935-2362 (Mon-Fri 9am-5pm EST)

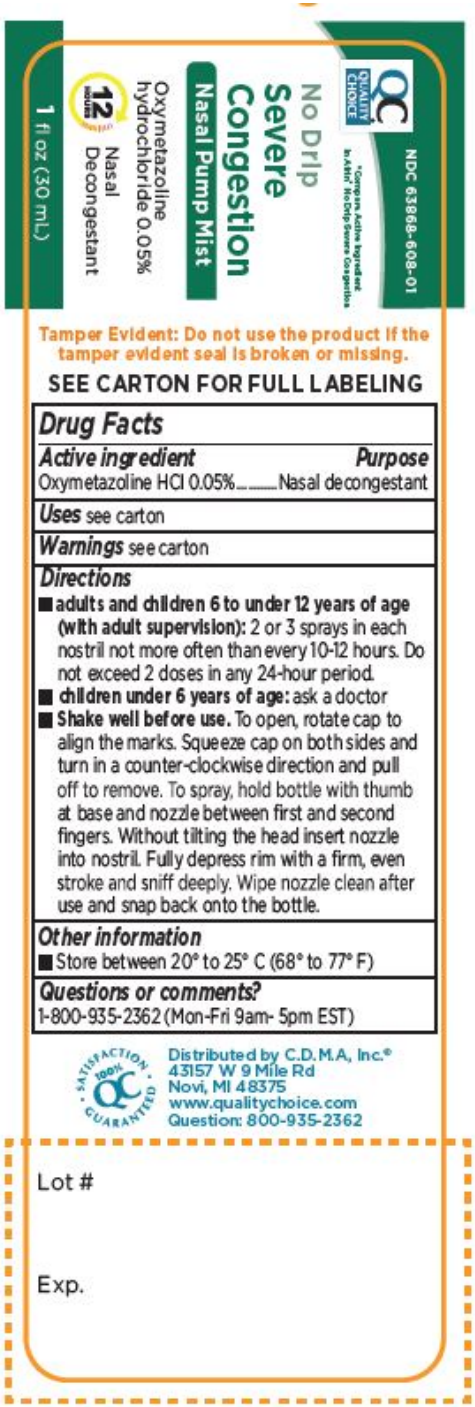
Inactive ingredients

avicel, benzalkonium chloride, benzyl alcohol, camphor, dibasic sodium phosphate, edetate disodium dihydrate, eucalyptol, menthol, monobasic sodium phosphate, polyethylene glycol, povidone, purified water

*This product is not manufactured or distributed by Bayer HealthCare LLC mdistributor of Afrin No Drip Severe Congestion

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 63868-608-01
QUALITY CHOICE
"Compare Active Ingredient to Afrin" No Drip Severe Congestion
No Drip
Severe
Congestion
Nasal Pump Mist
Oxymetazoline hydrochloride 0.05%
12 HOURS
Nasal Decongestant
1 fl oz (30 mL)
Tamper Evident: Do not use the product if the tamper evident seal is broken or missing.
SEE CARTON FOR FULL LABELING
Drug Facts
Active ingredient Purpose
Oxymetazoline HCl 0.05%..... Nasal decongestant
Uses see carton
Warnings see carton
Directions
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Lot #
Exp.

OXYMETAZOLINE HYDROCHLORIDE

oxymetazoline hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-608
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 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 94255I6E2T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EUCALYPTOL (UNII: RV6J6604TK)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-608-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/15/2021	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Registrant - Seaway Pharma Inc. (117218785)

Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma Inc.		117218785	manufacture(63868-608)

Revised: 8/2021 CHAIN DRUG MARKETING ASSOCIATION INC