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.

Nasal Decongestant

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 open, rotate cap to align the marks. Squeeze cap on both sides and tum 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 tiltlng 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˚C to 25˚C (68˚F to 77˚F)
- retain carton for future reference on full labeling

Inactive ingredients

- **No Drip Original Nasal Pump Mist- (NDC-63868-605-01)** avicel. benzalkonium chloride, benzyl alcohol. dibasic sodium phosphate, edetate disodium dihydrate, flavor, monobasic sodium phosphate, polyethylene glycol, povidone, purified water
- **No Drip Extra Moisturizing Nasal Pump Mist- (NDC-63868-676-01)** avicel. benzalkonium chloride, benzyl alcohol, dibasic sodium phosphate, edetate disodium dihydrate, glycerin, monobasic sodium phosphate, polyethylene glycol, povidone, purified water

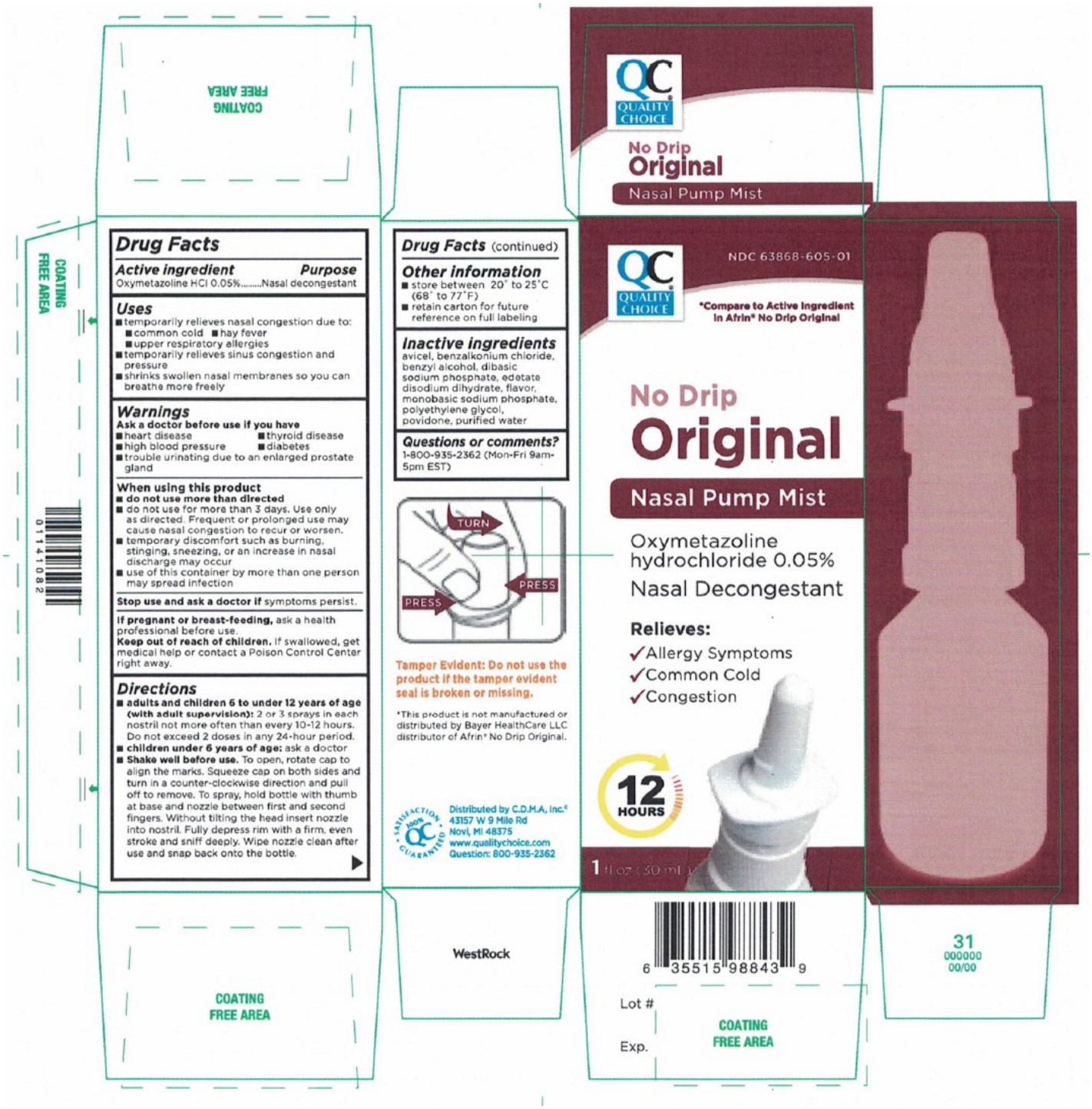
- Tamper Evident: Do not use the product if the temper evident seal is broken or missing.
- This product is not manufactured or distributed by Bayer HealthCare LLC distributor of Afrin Original Nasal Spray.

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

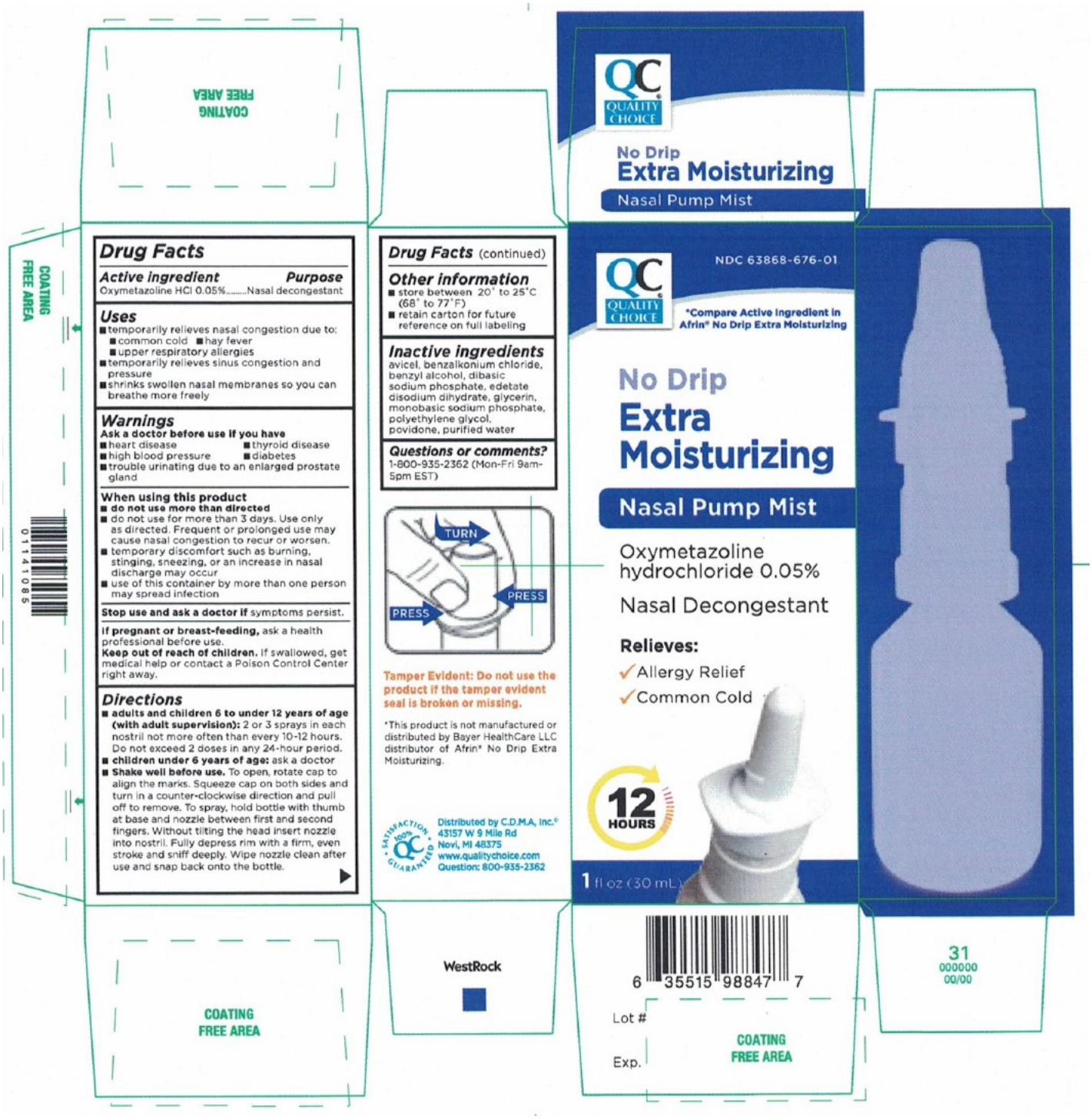
Distributed by C.D.M.A Inc.
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Question: 800-935-2362

PRINCIPAL DISPLAY PANEL

NDC-63868-**605**-01



NDC-63868-**676**-01



OXYMETAZOLINE HYDROCHLORIDE

oxymetazoline hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-605
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
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:63868-605-01	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	

OXYMETAZOLINE HYDROCHLORIDE

oxymetazoline hydrochloride spray

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BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
glycerin (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
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Labeler - CHAIN DRUG MARKETING ASSOCIATION INC. (011920774)

Registrant - Seaway Pharma Inc. (117218785)

Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma Inc.		117218785	manufacture(63868-605, 63868-676)

Revised: 8/2021 CHAIN DRUG MARKETING ASSOCIATION INC.