OXYMETAZOLINE HCL- oxymetazoline hcl spray
Seaway Pharma 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 SPRAY ORIGINAL 15mL and 30mL

Active Ingredient: Oxymetazoline HCl 0.05%

Purpose: Nasal Decongestant

Uses
Temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- shrinks swollen nasal membrances so you can breathe more freely.

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 (1-800-222-1222) right away.

Directions
- adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostrill 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: consult a doctor.

To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

- store between 20°C to 25°C (68° 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

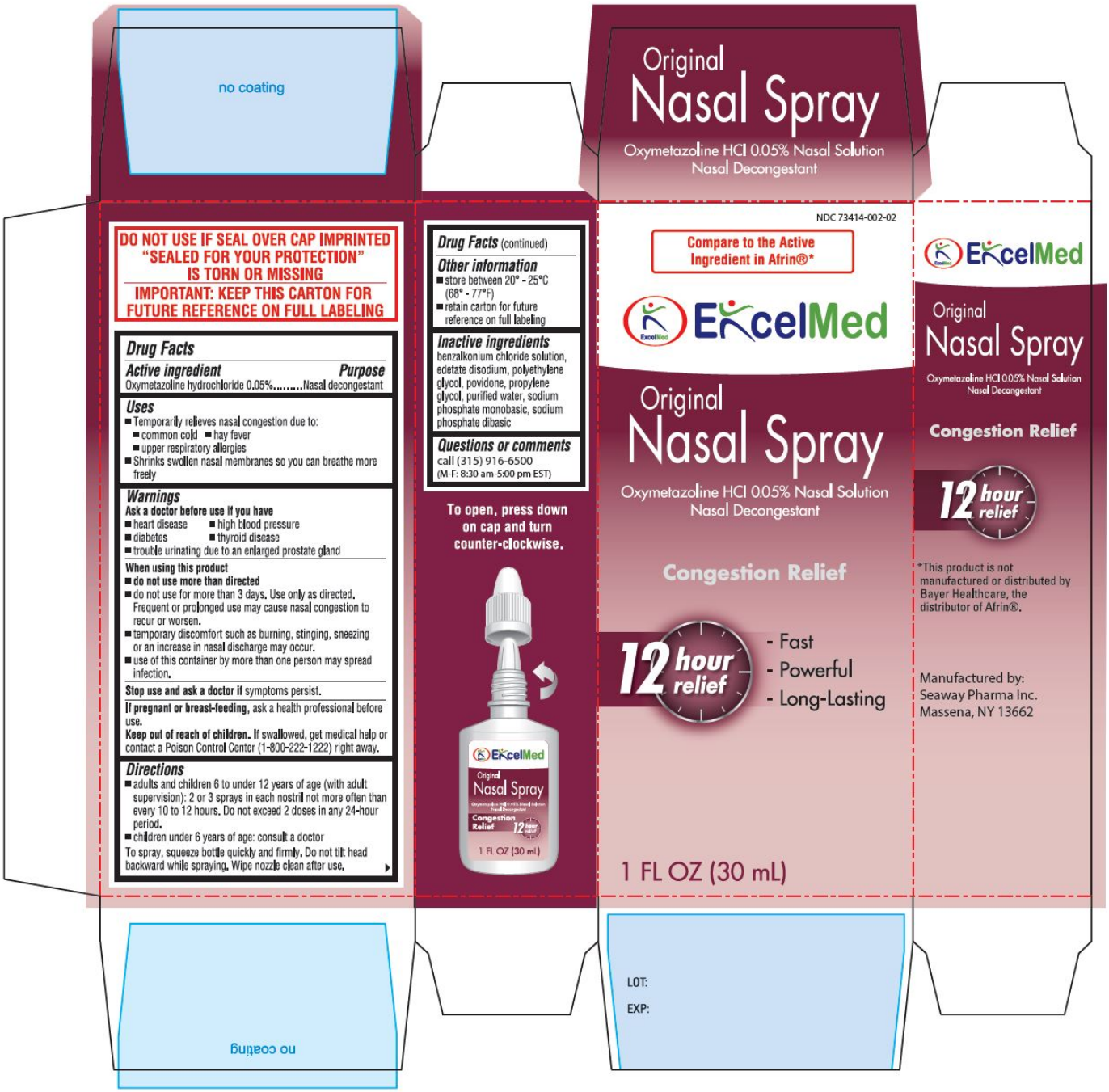
(pack: 30ml) NDC# 73414-002-02

(pack: 15ml) NDC# 73414-002-13

Manufactured by:

Seaway Pharma Inc.

Massena, NY 13662



OXYMETAZOLINE HCL

oxymetazoline hcl spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73414-002
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (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:73414-002-02	1 in 1 CARTON	01/01/2020	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:73414-002-17	1 in 1 CARTON	01/01/2020	
2		15 mL in 1 BOTTLE; 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	01/01/2020	

Labeler - Seaway Pharma Inc. (117218785)

Registrant - Seaway Pharma Inc. (117218785)

Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma Inc.		117218785	manufacture(73414-002)

Revised: 6/2020 Seaway Pharma Inc.