SEVERE NASAL- oxymetazoline hydrochloride 0.05% spray
ALAINA HEALTHCARE PRIVATE LIMITED

Severe Nasal Spray

Drug Facts

Active ingredient	***Purpose***
Oxymetazoline hydrochloride 0.05%	Nasal decongestant

Uses

temporarily relieves
- nasal congestion due to a cold, hay fever, or other upper respiratory allergies
- sinus congestion and pressure

Warnings

Ask a doctor before use if you have
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland

When using this product
- **do not exceed recommended dosage**
- Do not use this product 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 increased 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 & children 6 years & older (with adult supervision): 2 or 3 sprays in each nostril, not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24 hour period.
- Children 2 to under 6 years: ask a doctor.
- Children under 2 years: do not use.

Other information -do not exceed 25°C

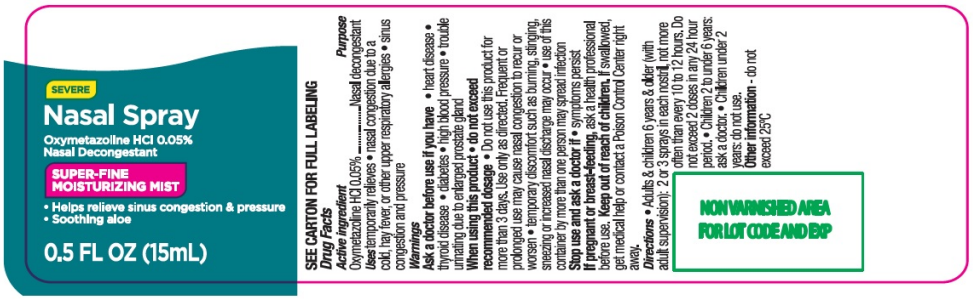
Inactive ingredients

aloe barbadensis leaf extract, benzalkonium chloride, disodium EDTA, polyethylene glycol, PVP, propylene glycol, purified water, sodium phosphate dibasic, sodium phosphste monobasic

Principal Display Panel

SEVERE Nasal Spray
Oxymetazoline HCl 0.05 %
Nasal Decongestant
SUPER-FINE Moisturizing MIST
- Helps relieve sinus congestion & pressure

- Soothing aloe
0.5 FL OZ (15mL)



SEVERE NASAL

oxymetazoline hydrochloride 0.05% spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73492-715
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73492-715-15	1 in 1 CARTON	09/15/2023	
1		15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/15/2023	

Labeler - ALAINA HEALTHCARE PRIVATE LIMITED (858720927)

Establishment

Name	Address	ID/FEI	Business Operations
ALAINA HEALTHCARE PRIVATE LIMITED		858720927	manufacture(73492-715)

Revised: 12/2023 ALAINA HEALTHCARE PRIVATE LIMITED