

# **CAREONE SEVERE CONGESTION NASAL- oxymetazoline hydrochloride spray, metered**

**American Sales Company**

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## **American Sales Company Severe Congestion Nasal Spray Drug Facts**

### **Active ingredient**

Oxymetazoline hydrochloride 0.05%

### **Purpose**

Nasal decongestant

### **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**

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

**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 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- children under 6 years of age: ask a doctor

To Use: Shake well before use. Hold white tabs, SQUEEZE grooved area of cap FIRMLY and turn counter clockwise. Before using the first time, prime metered pump by depressing pump firmly several times. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use. Secure cap after use.

**Other information**

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

**Inactive ingredients**

benzalkonium chloride solution, benzyl alcohol, camphor, dibasic sodium phosphate, edetate disodium, eucalyptol, menthol, microcrystalline cellulose and carboxymethylcellulose sodium, monobasic sodium phosphate, polyethylene glycol, povidone, propylene glycol, purified water

**Questions or comments?**

1-800-719-9260

**Package/Label Principal Display Panel**

Compare to the active ingredient in Afrin® No Drip Severe Congestion

SEVERE CONGESTION NASAL SPRAY

Oxymetazoline HCl 0.05%

Nasal Decongestant

12hr

No Drip - Maximum Strength

Plus Menthol

Fast, Powerful Congestion Relief

For Colds & Allergies

Won't Drip From Nose or Down Throat

Pump Mist

Gluten Free

OUR PHARMACISTS RECOMMEND

1 FL OZ (30mL)



## CAREONE SEVERE CONGESTION NASAL

oxymetazoline hydrochloride spray, metered

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-108
<b>Route of Administration</b>	NASAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)			OXYMETAZOLINE HYDROCHLORIDE	.05 g in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)				
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
EUCALYPTOL (UNII: RV6J6604TK)				
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)				
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0K00R)				
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
Product Characteristics				
Color	WHITE (off white)		Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-108-10	1 in 1 CARTON	08/31/2016	
1		30 mL in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	08/31/2016		

**Labeler** - American Sales Company (809183973)