

CAREONE SEVERE CONGESTION NASAL- oxymetazoline hydrochloride spray
American Sales Company

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.

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
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in Afrin® No Drip Severe Congestion*

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OUR PHARMACISTS RECOMMEND

1 FL OZ (30mL)

Actual Size

DO NOT USE IF PRINTED MESSAGE IS BROKEN OR MISSING

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*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Afrin® No Drip Severe Congestion.

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SQUEEZE grooves FIRMLY while turning

Hold white tabs **FIRMLY**

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CAREONE SEVERE CONGESTION NASAL

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-108
Route of Administration	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 (UNII: GR686LBA74)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EUCALYPTOL (UNII: RV6J6604TK)	
MENTHOL (UNII: L7T10EIP3A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
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; 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	08/31/2016	

Labeler - American Sales Company (809183973)

