

DG HEALTH SINUS SEVERE- oxymetazoline hydrochloride spray
Dolgenercorp, LLC

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.

Dolgenercorp, LLC Sinus Severe Drug Facts

Active ingredient

Oxymetazoline HCl 0.05%

Purpose

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 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

Shake well before use. Hold white tabs, SQUEEZE grooved area of cap FIRMLY and turn counter clockwise. Before using for the first time, prime the pump by firmly depressing its rim several times. Hold container with thumb at base and nozzle between first and second fingers. Without tilting your head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and inhale deeply. Secure cap after use.

adults & children 6 yrs. & 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 24 hours.
children 2 to under 6 yrs.	ask a doctor
children under 2 yrs.	do not use

Other information

- store at 20-25°C (68-77°F)

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?

1-888-309-9030

Package/Label Principal Display Panel

DG™ |health

Compare to the active ingredient of Sinex® Severe

Sinus Severe

Oxymetazoline HCl 0.05%

Nasal Decongestant

Sinus Congestion & Pressure

Fast & Powerful Relief

#1 Doctor recommended

Adult Nasal Spray

active ingredient

12 HOUR RELIEF

Ultra Fine Mist With Menthol

1 FL OZ (30 mL)



DG HEALTH SINUS SEVERE

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-696
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
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 FORM (UNII: K679OBS311)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

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:55910-696-10	1 in 1 CARTON	05/24/2018	
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	05/24/2018	

Labeler - Dolgencorp, LLC (068331990)