

12 HOUR ORIGINAL NASAL DECONGESTANT- nasal spray liquid

Sheffield Pharmaceuticals 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.

Drug Facts

Active Ingredient

Oxymetazoline Hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- sinusitis
- upper respiratory allergies
- Shrink swollen membranes so you can breathe more freely

Warnings

Ask a Doctor before use if you have

- heart disease
- high blood pressure
- diabetes
- thyroid disease
- trouble urinating due to enlarged prostate gland.

When using this product

- **Do not use more than directed**
- do not use for more than three 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.

ask a health professional before use.

Keep out of the reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

- Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more 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 backwards while spraying, wipe nozzle clean after use.

Other information

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

Inactive Ingredients:

benzalkonium chloride, edetate disodium, glycerin, polyethylene glycol, povidone, propylene glycol, sodium phosphate dibasic, sodium phosphate monobasic, water

Principal display panel- Bottle

Sheffield Pharmaceutical NDC 11527-140-55

Original Nasal Spray

Oxymetazoline HCL 0.05%

12hour relief of Nasal congestion due to:

- **common cold**
- **hay fever**
- **sinusitis**
- **upper respiratory allergies**

30 mL (1.01 FL OZ)



NDC 11527-140-55

Compare to active ingredient in Afrin®*

Original

Nasal Spray

Oxymetazoline HCl 0.05%

12 hour relief of Nasal congestion due to:

- common cold
- hay fever
- sinusitis
- upper respiratory allergies



30mL (1.01 FL OZ)

7002698B

Principal display panel- Bottle back label

SEE CARTON FOR FULL LABELING.

USES: See carton.

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.

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.

Active Ingredient: Oxymetazoline hydrochloride, 0.05%

Store between 20° to 25°C (68° to 77°F)

Made in USA

70020412B

SEE CARTON FOR FULL LABELING.

USES: See carton.

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.

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Principal display panel -Carton

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nasal spray liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-140
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	50 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW)	

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
POVIDONE K29/32 (UNII: 390RMW2PEQ)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-140-55	1 in 1 CARTON	05/30/2014	
1		30 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 final	part341	05/30/2014	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(11527-140)

Revised: 11/2021

Sheffield Pharmaceuticals LLC