

12 HOUR ORIGINAL NASAL DECONGESTANT- nasal spray liquid
Preferred Pharmaceuticals Inc.

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

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

Principal display panel- Bottle

<p>Nasal Decongestant 12-Hour Spray Compare to Afrin</p> <p>Active Ingredient Oxymetazoline HCl, 0.05%</p> <p>Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: Faria LLC dba Sheffield Pharmaceutical Prod#:</p> <p>Warning 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 product 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 this and all medication out of the reach of children. Store between 20° and 25°C (68° to 77°F). Retain carton for future reference.</p>	<p>PREFERRED Pharmaceuticals, Inc. <small>Amherst, Co 02827</small></p> <p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p> <p>Directions English Take _____ sprays in each nostril every _____ hours Use as directed by your doctor</p> <p>Instrucciones Espanol: La Toma _____ rocia cada _____ horas Usó según lo dirigido por su doctor</p>	<p>Nasal Decongestant 12-Hour Spray Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>Nasal Decongestant 12-Hour Spray Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>Nasal Decongestant 12-Hour Spray Qty: Ins: Insurance NDC: Lot#: Bat#:</p> <p>Nasal Decongestant 12-Hour Spray Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	<p>Log</p> <p>Chart</p> <p>Billing</p> <p>Patient</p>
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Lee

Relieves Congestion

Nasal Spray original 12 hour relief

Oxymetazoline HCL Nasal Solution Nasal Decongestant

1 FL OZ (30 ml)

Relabeled By: Preferred Pharmaceuticals Inc.

12 HOUR ORIGINAL NASAL DECONGESTANT
nasal spray liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7075(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, UNSPECIFIED FORM (UNII: 3980JIH2SW)				
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
POVIDONE K30 (UNII: U725QWY32X)				
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7075-3	1 in 1 CARTON	01/02/2018	
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	01/02/2018		

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7075)