12 HOUR ORIGINAL NASAL DECONGESTANT- nasal spray liquid
Sheffield Pharmaceuticals LLC

Sheffield 12HR Nasal Spray

Drug Facts

Active Ingredient
Oxymetazoline Hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

Tempoarily relieves nasal congestion due to:

- common cold
- hay fever
- sinusitis
- upper respiroty allergies
- Shribnk swollen membranes so you can breathemore freely

Warnings

Ask a Doctor before use if you have

- heart diease
- high blood pressure
- diabetes
- thyiod diease
- trouble urinating due to enlarged rostate gland.

When using this product

- **Do not use more than directed**
- do not use for more than three days, Use onyl 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 thna 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)

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.

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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: 3980JIH2SW)	

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 Drug	M012	05/30/2014	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Establishment

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

Revised: 10/2023 Sheffield Pharmaceuticals LLC