NO DRIP SEVERE NASAL MIST- oxymetazoline spray liquid Sheffield Pharmaceuticals LLC

Drug Facts

Active Ingredient

Oxymetazoline Hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiroty allergies
- temporarily relieves sinus congestion and pressure
- Shrinks swollen membranes so you can breathe more 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 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 the reach of children

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

Directions

- Before using for the first time, remove the protective cap form the tip and prime the 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 nostrile. Fully depress rim with a firm and even stroke, and sniff deeply.
- Wipe nozzle clean after use.
- 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.

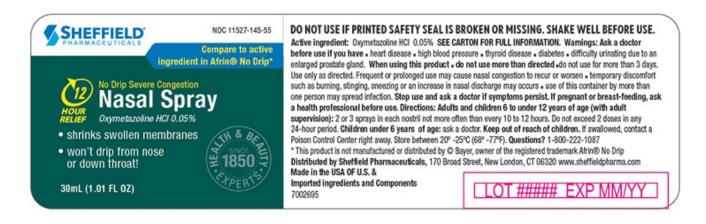
Other information

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

Inactive Ingredients

Benzalkonium Chloride, Camphor, Cellulose Gum, Disodium EDTA, Disodium Phosphate, Eucalyptol, Glycerin, Menthol, Microcrystalline Cellulose and Carboxymethylcellulose Sodium, PEG-6, Povidone, Propylene Glycol, Sodium Phosphate, Water (purified)

Principal Panel 0.5 FLOZ Bottle



Sheffield NDC 11527-145-55

No Drip Severe Nasal Mist

Nasal Spray
Oxymetazoline HCL 0.05%
12 hour Nasal Spray
Net Wt 30 ml (1.01 FLOZ)



DO NOT USE IF PRINTED SAFETY SEAL IS BROKEN OR MISSING. SHAKE WELL BEFORE USE.

Active ingredient: Oxymetazoline HCI 0.05% SEE CARTON FOR FULL INFORMATION. Warnings: Ask a doctor before use if you have - heart disease - high blood pressure - thyroid disease - diabetes - difficulty 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 occurs - 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. 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. Keep out of reach of children. If swallowed, contact a Poison Control Center right away. Store between 20° -25°C (68° -77°F). Questions? 1-800-222-1037 * This product is not manufactured or distributed by © Bayer, owner of the registered trademark Afrin® No Drip Distributed by Sheffield Pharmaceuticals, 170 Broad Street, New London, CT 06320 www.sheffieldpharma.com Made in the USA 0F U.S. &

Imported ingredients and Components 7002695

LOT ##### EXP MM/YY



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Made in the USA 0F U.S. & Imported ingredients and Components 7002695

LOT ##### EXP MM/YY

Principal display panel- Carton label

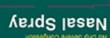
Sheffield No Drip Severe Nasal Mist NDC 11527-145-55

Nasal Spray

Oxymetazoline HCL 0.05%

12 hour Nasal Spray

Net Wt 30ml (1.01FLOZ)





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Drug Facts
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Drug Facts (continued)

Other Information

- store between 20" -25°C (55" -27°F)

- Retain carton for future reference on full labeling

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Inactive Ingredients
Serzistenium Ostoride,
Campino Certaines Gare,
Desclum 19th, Ostorium,
Plocapide Eustophio,
Vaporin, Martin, Desclum 19th,
Vaporin, Martin, Filipid,
Vaporin, Martin, Filipid,
Filipid, Plocapid,
Filipid, Plocapid,
Filipid, Plocapid,
Filipid, Sodium,
Plocapida, Midder gurthod

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Made in USA

PROTEST LINEAR There are if

"This product is not monafactured or distributed by O Bayer, owner of the registered trademark Afrind's No Drip.

NOC 11527-145-55

Compare to active ingredient in Africa No Brip*

No Drip Severe Congestion

SHEFFIELD

Nasal Spray Oxymetazoline HCI 0.05%

12 hour relief of severe congestion due to:

- · common cold
- · upper respiratory allergies
- · shrinks swollen membranes

Won't Drip From Nose or Down Throat!



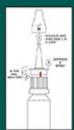


30mL (1.01 FL 0Z)





- Squeeze the size of the cap and hald the cap counterconstants
 Align the law on the grows at the base of the pump (red) in the pocture.
 Depress and spray



54340508



NO DRIP SEVERE NASAL MIST

oxymetazoline spray liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11527-145 |
| Route of Administration | NASAL | | |

| Active Ingredient/Active Moiety | | | |
|--|---------------------------------|--------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY) | OXYMETAZ OLINE HYDROCHLORIDE | 50 mg in 100 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW) | |
| SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| WATER (UNII: 059QF0KO0R) | |
| POVIDONE (UNII: FZ989GH94E) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| EUCALYPTOL (UNII: RV6J6604TK) | |

| F | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:11527- 145-55 | 1 in 1 CARTON | 12/22/2020 | |
| 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 | 12/22/2020 | |
| | | | |

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

| Establishment | | | | |
|------------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Sheffield Pharmaceutical LLC | | 151177797 | manufacture(11527-145) | |

Revised: 11/2023 Sheffield Pharmaceuticals LLC