SINUFRIN PLUS NEILMED- oxymetazoline hydrochloride spray
NeilMed 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 Ingredients

0.05% Oxymetazoline Hydrochloride

Warnings

- Do not use this product for more than 3 consecutive days.Use only as directed.
- Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor.
- Do not use this product if you have heart disease, high blood pressure, thyroid disease or diabetes unless directed by a doctor.

Directions for Dosing

* Adults and children 6 to 12 years of age (with adult supervision): Per dose, 2 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: consult a doctor

Uses

Temporarily relieves nasal congestion due to common cold, sinus infections, hay fever, upper respiratory allergies.

Other Information

Store between 20 to 40 °C (68 to 104 °F)
Retain carton for future reference on full labeling

Warnings

KEEP OUT OF REACH OF CHILDREN. If Swallowed,get medical help or contact a Poison Control Center right away.

Do not use this product for more than 3 consecutive days.

Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor.

Other Information

- Keep head in an upright position for use.
- Do not tilt head backward while spraying.
- Wipe nozzle clean after each use.

Warnings

Stop use and ask a doctor if symptoms of nasal congestion persist after 3 days.

Adult males with prostate disease, do not use this product.

Warnings

If pregnant or breast-feeding, ask health care professional before use.

Warnings

This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge.
The use of this container by more than one person may spread infection.

Inactive ingredients

Propylene glycol, glycerin, sodium chloride, hyaluronic acid, aloe vera, allantoin, sodium bicarbonate USP, benzalkonium chloride, edetate disodium, purified water

Principle Display

Imag of Bottle

Box Label

uses

temporarily relieves nasal congestion due to:

common cold

sinusitis

hay fever

upper respiratory allergies

SINUFRIN PLUS NEILMED

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:13709-232
Route of Administration	NASAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Oxymetazoline Hydrochloride (OXYMETAZOLINE)	Oxymetazoline Hydrochloride	7.5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
Benzalkonium Chloride	
Propylene Glycol	
Sodium Chloride	
water	
Sodium Bicarbonate	
Glycerin	
Aloe	
Allantoin	
Hydrochloric Acid	
EDETATE DISODIUM	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-232-06	15 mL in 1 BOTTLE		
2	NDC:13709-232-05	15 mL in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/15/2012	

Labeler - NeilMed Pharmaceuticals, Inc. (783557783)

Establishment

Name	Address	ID/FEI	Business Operations

NeilMed Pharmaceuticals, Inc.		783557783	manufacture(13709-232)