SINUFRIN 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

Uses

temporarily relieves nasal congestion due to: common cold n sinusitis, hay fever, upper respiratory allergies

Warnings

Do not exceed recommended dosage. 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.

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.

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.

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

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 using this product for more than 3 consecutive days. Stop and ask your doctor if symptoms of nasal congestion persist after using 3 consecutive days.

Warnings

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

Uses

temporarily relieves nasal congestion due to: common cold n sinusitis, hay fever, upper respiratory allergies.

Inactive Ingredients

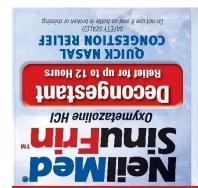
Sodium chloride, sodium bicarbonate, propylene glycol, edetate disodium, benzalkonium chloride, purified water

Principal Display label





Box label



Oxymetazoline Hydrochloride

Fast Acting

Nasal Decongestant

12 Hour Relief

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UNITED KINGDOM

Drug Facts

Active Ingredients Purpose
Oxymetazoline hydrochloride 0.05% Nasal Decongestant
Each full spray releases 0.1 mL of solution

Uses

- temporarily relieves nasal congestion due to:
- common cold sinusitis ■ hay fever
 - upper respiratory allergies

∆ Warnings

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 The use of this container by more than one person may
- spread infection.

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- Do not use this product if you have heart disease, high blood pressure, thyroid disease or diabetes unless
- directed by a doctor.

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- professional before use.

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Inactive Ingredients

Sodium chloride, sodium bicarbonate, propylene glycol, edetate disodium, benzalkonium chloride, purified wate

Oxymetazoline HCl

Decongestant Relief for up to 12 Hours

NeilMed

SinuFrin

lecongestant

QUICK NASAL CONGESTION

RELIEF

QUICK New! NASAL CONGESTION RELIEF

> **NeilMed®** SinuFrin-**Nasal Spray** starts to work in seconds, providing up to 12 hours of nasal decongestion.

No drowsiness 12 hour relief (Approximately)

Oxymetazoline HCl

Decongestant Relief for up to 12 Hours



QUICK NASAL CONGESTION RELIEF



QUICK NASAL CONGESTION RELIEF



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SINUFRIN NEILMED

oxymetazoline hydrochloride spray

Product Information

HUMAN OTC DRUG LABEL NDC:13709-231 Product Type Item Code (Source)

Route of Administration NASAL DEA Schedule CII

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDRO CHLO RIDE (OXYMETAZOLINE)	OXYMETAZOLINE HYDROCHLORIDE	7.5 mg in 15 mL

Inactive Ingredients	
Ingredient Name	Strength
SO DIUM CHLO RIDE	
SO DIUM BICARBO NATE	
PROPYLENE GLYCOL	
EDETATE DISO DIUM	
BENZALKO NIUM CHLO RIDE	
WATER	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:13709-231-07	15 mL in 1 BOTTLE		
2 NDC:13709-231-04	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)

Registrant - NeilMed Pharmaceuticals Inc (783557783)

Establishment				
Name	Address	ID/FEI	Business Operations	
NeilMed Pharmaceuticals Inc		783557783	manufacture(13709-231)	

Revised: 9/2012 NeilMed Pharmaceuticals Inc