

SINUFRI^N 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

<p>Drug Facts</p> <table border="1"><thead><tr><th>Active Ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Oxymetazoline hydrochloride 0.05%</td><td>Nasal Decongestant</td></tr></tbody></table> <p>Each full spray releases 0.1 mL of solution</p> <p>Uses</p> <p>temporarily relieves nasal congestion due to: ■ common cold ■ sinusitis ■ hay fever ■ upper respiratory allergies</p> <p>Warnings</p> <ul style="list-style-type: none">■ 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.■ 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.	Active Ingredients	Purpose	Oxymetazoline hydrochloride 0.05%	Nasal Decongestant	 <p>NeilMed SinuFrinTM Oxymetazoline HCl Nasal Solution Nasal Decongestant</p> <p>Decongestant Relief for up to 12 Hours</p> <p>QUICK NASAL CONGESTION RELIEF</p> <p>12 Hour Relief 0.5 fl oz (15 mL)</p>	<ul style="list-style-type: none">■ If pregnant or breast feeding, ask a health professional before use.■ Keep out of reach of children. If ingested, get medical help or contact a Poison Control Center right away. <p>Directions for Dosing</p> <ul style="list-style-type: none">■ 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 <p>Other information</p> <ul style="list-style-type: none">■ Store between 20 to 40 °C (68 to 104 °F)■ Retain carton for future reference on full labeling■ Keep head in an upright position for use.■ Do not tilt head backward while spraying.■ Wipe nozzle clean after each use. <p>inactive ingredients</p> <p>Sodium chloride, sodium bicarbonate, propylene glycol, edetate disodium, benzalkonium chloride, purified water.</p> <p>NDC 13709-231-07</p> <p>Questions/Concerns 1 877 477 8633</p> <p>Manufactured By NeilMed® Pharmaceuticals 601 Aviation Blvd, Santa Rosa, CA 95403 USA</p>
Active Ingredients	Purpose					
Oxymetazoline hydrochloride 0.05%	Nasal Decongestant					

Box label

©NeilMed® 2000-2012 6024-ENU-US_REV02_GP20120921_AP

Do not use if seal on bottle is broken or missing.
SAFETY SEALED.

**QUICK NASAL
CONGESTION RELIEF**

Decongestant
Relief for up to 12 Hours

**NeilMed[®]
SinuFrin[™]**
Oxymetazoline HCl

Oxymetazoline Hydrochloride

Fast Acting

Nasal Decongestant

12 Hour Relief

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

- **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.
- 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.
- **If pregnant or breast-feeding**, ask a health care professional before use.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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

Inactive Ingredients

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

**NeilMed[®]
SinuFrin[™]**
Oxymetazoline HCl

Decongestant
Relief for up to 12 Hours



New!

**QUICK
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)

Contents: 1 Spray Bottle
0.5 fl oz (15 mL)

**NeilMed[®]
SinuFrin[™]**
Oxymetazoline HCl

Decongestant
Relief for up to 12 Hours



New!

**QUICK
NASAL
CONGESTION
RELIEF**



Contents: 1 Spray Bottle
0.5 fl oz (15 mL)

**NeilMed[®]
SinuFrin[™]**

USA - HEAD OFFICE / MFG
601 Aviation Blvd, Santa Rosa, CA 95403
Toll Free: 1(877) 477-8633
Tel: +1(707) 525-3784
Fax: +1(707) 525-3785
www.neilmed.com

CANADA
PO Box #3553, Markham, ON L3R 6G8
Toll Free: 1(877) 477-8633
Tel: +1(905) 480-0202
Fax: +1(905) 480-0201

UNITED KINGDOM
PO Box #2853, Coulsdon, Surrey, CR5 2WN, UK
Toll Free: +44 (0) 800 032 6073
Tel: +44 (0)208 660 9447
Fax: +44 (0)207 900 6414
www.neilmed.co.uk

IRELAND/EUROPE
PO Box #2853, Coulsdon, Surrey, CR5 2WN, UK
Toll Free: 00800 722 00027
Fax: +44 (0)207 900 6414

AUSTRALIA
12/354 Chisholm Rd, Auburn, NSW 2144
Toll Free: 1800 158 900
Tel: +61 1300 652 148
Fax: +61 (0)3 8677 9989
www.neilmed.com.au

NEW ZEALAND
PO Box #27310, Mount Roskill, Auckland 1440
Toll Free: 0800 634 5633
Tel: +64 (0)9 570 7279
Fax: +64 (0)9 353 1430

SINGAPORE
66 Tannery Lane, #01-02D
Sindo Industrial Building,
Singapore 347805
Tel: +65 (0)6 221 8948
Fax: +65 (0)6 491 5930

INDIA
Suite 1 C, #118, Neil Rao Towers,
Road #3 EPIP Zone,
Whitefield, Bangalore 560066
Tel: +91 80 4161 3512
Fax: +91 80 4160 5707



MANUFACTURED BY



601 Aviation Blvd, Santa Rosa, CA 95403 USA
1 (877) 477-8633

ISO 13485: 2003 International Accreditation
Quality Management System Certified Company

© NeilMed[®] 2000-2012 All Rights Reserved
NDC 13709-231-04



7 05928 09001 1



2830-ENU-US_rev#3
PP20120820_AP

SINUFRIN NEILMED

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-231
Route of Administration	NASAL	DEA Schedule	CII

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	7.5 mg in 15 mL

Inactive Ingredients	
Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
WATER (UNII: 059QF0KO0R)	

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; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NDC:13709-231-04	15 mL in 1 BOX; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

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		799295915	manufacture(13709-231)