

**SINUFRIN NEILMED- oxymetazoline hydrochloride spray**  
**NeilMed Pharmaceuticals Inc**

-----

**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><b>Drug Facts</b></p> <p><b>Active Ingredients</b> Oxymetazoline hydrochloride 0.05%    <b>Purpose</b> Nasal Decongestant</p> <p>Each full spray releases 0.1 mL of solution</p> <p><b>Uses</b> temporarily relieves nasal congestion due to: ■ common cold ■ sinusitis ■ hay fever ■ upper respiratory allergies</p> <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>■ Do not exceed recommended dosage.</li> <li>■ This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge.</li> <li>■ The use of this container by more than one person may spread infection.</li> <li>■ 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.</li> <li>■ Do not use this product if you have heart disease, high blood pressure, thyroid disease or diabetes unless directed by a doctor.</li> <li>■ Adult males with prostate disease, do not use this product.</li> </ul>	<div>  <p><i>Oxymetazoline HCl Nasal Solution Nasal Decongestant</i></p> <p><b>Decongestant</b> Relief for up to 12 Hours</p> <p><b>QUICK NASAL CONGESTION RELIEF</b></p> <p><b>12 Hour Relief</b> 0.5 fl oz (15 mL)</p> </div>	<ul style="list-style-type: none"> <li>■ If pregnant or breast feeding, ask a health professional before use.</li> <li>■ Keep out of reach of children. If ingested, get medical help or contact a Poison Control Center right away.</li> </ul> <p><b>Directions for Dosing</b></p> <ul style="list-style-type: none"> <li>■ 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.</li> <li>■ Children under 6 years of age: consult a doctor</li> </ul> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>■ Store between 20 to 40 °C (68 to 104 °F)</li> <li>■ Retain carton for future reference on full labeling</li> <li>■ Keep head in an upright position for use.</li> <li>■ Do not tilt head backward while spraying.</li> <li>■ Wipe nozzle clean after each use.</li> </ul> <p><b>Inactive Ingredients</b> Sodium chloride, sodium bicarbonate, propylene glycol, edetate disodium, benzalkonium chloride, purified water.</p> <p><b>NDC 13709-231-07</b></p> <p><b>Questions/Concerns 1 877 477 8633</b></p> <p><b>Manufactured By NeilMed® Pharmaceuticals</b> 601 Aviation Blvd, Santa Rosa, CA 95403 USA</p>
---	---	---

©NeilMed® 2000-2012 6024-ENU-US\_REV02\_GP20120921\_AP

**Box label**

**NeilMed<sup>®</sup> SinuFrin<sup>™</sup>**  
Oxymetazoline HCl

**Decongestant**  
Relief for up to 12 Hours

**QUICK NASAL CONGESTION RELIEF**

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

**NeilMed<sup>®</sup> SinuFrin<sup>™</sup>**  
Oxymetazoline HCl

**Decongestant**  
Relief for up to 12 Hours

**QUICK NASAL CONGESTION RELIEF**

New!

**NeilMed<sup>®</sup> SinuFrin<sup>™</sup> 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<sup>®</sup> SinuFrin<sup>™</sup>**  
Oxymetazoline HCl

**Decongestant**  
Relief for up to 12 Hours

**QUICK NASAL CONGESTION RELIEF**

New!

**NeilMed<sup>®</sup> SinuFrin<sup>™</sup> 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<sup>®</sup> SinuFrin<sup>™</sup>**

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  
www.neilmed.com

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 (03) 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  
**NeilMed<sup>®</sup>**  
PHARMACEUTICALS, INC.  
601 Aviation Blvd, Santa Rosa, CA 95403 USA  
**1 (877) 477-8633**  
ISO 13485: 2003 International Accreditation  
Quality Management System Certified Company  
© NeilMed<sup>®</sup> 2000-2012 All Rights Reserved  
NDC 13709-231-04






7 05428 04001 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		

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

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

Product Characteristics			
<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

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)	07/15/2012	
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)	07/15/2012	
3	NDC:13709-231-12	1 in 1 CARTON	04/21/2021	
3		30 mL in 1 BOTTLE; 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	07/15/2012	

**Labeler** - NeilMed Pharmaceuticals Inc (799295915)

**Registrant** - NeilMed Pharmaceuticals Inc (799295915)

Establishment			
Name	Address	ID/FEI	Business Operations

NeilMed Pharmaceuticals Inc		799295915	manufacture(13709-231)
-----------------------------	--	-----------	------------------------

Revised: 1/2024

NeilMed Pharmaceuticals Inc