

SINUFNIN 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

uses

temporarily relieves nasal congestion due to:

common cold

sinusitis

hay fever

upper respiratory allergies

Principle Display

Image of Bottle

<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 0.15 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® SinuFrin NO DRIP Plus™ Decongestant Relief for up to 12 Hours Moisturizing Gel with Sodium Hyaluronate & Aloe Vera</p> <p><i>Oxymetazoline HCl Nasal Solution-Nasal Decongestant plus Sodium Hyaluronate & Aloe Vera</i></p> <p>QUICK NASAL CONGESTION RELIEF 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 Propylene glycol, glycerin, sodium chloride, hyaluronic acid, aloe vera, allantoin, sodium bicarbonate, benzalkonium chloride, edetate disodium, purified water.</p> <p>NDC 13709-232-06 Questions/Concerns 1 877 477 8633 Manufactured By NeilMed® Pharmaceuticals 601 Aviation Blvd, Santa Rosa, CA 95403 USA</p>
Active Ingredients	Purpose					
Oxymetazoline hydrochloride 0.05%	Nasal Decongestant					

Box Label

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

With Sodium Hyaluronate & Aloe Vera
Moisturizing Gel
Relief for up to 12 Hours
Decongestant
NO DRIP Plus™
SinuFrin
NeilMed®

Oxymetazoline Hydrochloride	Fast Acting	Nasal Decongestant	12 Hour Relief		
<p>Drug Facts</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Active Ingredients Oxymetazoline hydrochloride 0.05% Each full spray releases 0.15 mL of solution</td> <td style="width: 50%;">Purpose Nasal Decongestant</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves nasal congestion due to: <ul style="list-style-type: none"> ■ common cold ■ sinusitis ■ hay fever ■ upper respiratory allergies <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. ■ 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. <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 Propylene glycol, glycerin, sodium chloride, hyaluronic acid, aloe vera, allantoin, sodium bicarbonate USP, benzalkonium chloride, edetate disodium, purified water</p>	Active Ingredients Oxymetazoline hydrochloride 0.05% Each full spray releases 0.15 mL of solution	Purpose Nasal Decongestant	<p>NeilMed® SinuFrin NO DRIP Plus™ Decongestant Relief for up to 12 Hours Moisturizing Gel with Sodium Hyaluronate & Aloe Vera</p> <p>Oxymetazoline HCl</p> <p>New! QUICK NASAL CONGESTION RELIEF</p> <p>NeilMed® SinuFrin Plus™ Nasal Gel Spray starts to work in seconds, providing up to 12 hours of nasal decongestion.</p> <p>No drowsiness</p> <p>Contents: 1 Spray Bottle 0.5 fl oz (15 mL)</p> 	<p>NeilMed® SinuFrin NO DRIP Plus™ Decongestant Relief for up to 12 Hours Moisturizing Gel with Sodium Hyaluronate & Aloe Vera</p> <p>Oxymetazoline HCl</p> <p>New! QUICK NASAL CONGESTION RELIEF</p> <p>NeilMed® SinuFrin Plus™ Nasal Gel Spray</p> <p>NASAL GEL SPRAY 12 HOUR RELIEF</p> <p>Contents: 1 Spray Bottle 0.5 fl oz (15 mL)</p> 	<p>NeilMed® SinuFrin Plus™</p> <p>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</p> <p>CANADA PO Box #3553, Markham, ON L3R 6G8 Toll Free: 1(877) 477-8633 Tel: +1(905) 480-0202 Fax: +1(905) 480-0201</p> <p>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</p> <p>IRELAND/EUROPE PO Box #2853, Coulsdon, Surrey, CR5 2WN, UK Toll Free: 00800 722 00027 Fax: +44 (0)207 900 6414</p> <p>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</p> <p>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</p> <p>SINGAPORE 66 Tannery Lane, #01-02D Sindo Industrial Building, Singapore 347805 Tel: +65 (0)6 221 8948 Fax: +65 (0)6 491 5930</p> <p>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</p>
Active Ingredients Oxymetazoline hydrochloride 0.05% Each full spray releases 0.15 mL of solution	Purpose Nasal Decongestant				

MANUFACTURED BY

NeilMed®
PHARMACEUTICALS, INC.
601 Aviation Blvd, Santa Rosa, CA 95403 USA
1 (877) 477-8633
ISO 13485: 2003 International Accreditation
Quality Management System Certified Company
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NDC 13709-232-05



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SINUFRIN PLUS NEILMED

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-232
Route of Administration	NASAL		

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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0K00R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE (UNII: V5VD430YW9)	
ALLANTOIN (UNII: 344S277G0Z)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-232-06	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:13709-232-05	15 mL in 1 BOX; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	07/15/2012	

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. (799295915)**Establishment**

Name	Address	ID/FEI	Business Operations
NeilMed Pharmaceuticals, Inc.		799295915	manufacture(13709-232)