

PREFERRED PLUS 12 HOUR NASAL EXTRA MOISTURIZING- oxymetazoline hydrochloride spray

Kinray

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 ingredient

Oxymetazoline Hydrochloride, 0.05%

Purpose

Nasal Decongestant

Uses

- Temporarily relieves nasal decongestion due to: common cold, hay fever, sinusitis, upper respiratory allergies
- Shrinks swollen nasal membranes so you can breathe more freely

Warnings

As a doctor before use if you have

- Heart disease
- High blood pressure
- Diabetes
- Thyroid disease
- Trouble urinating due to an enlarged prostate gland

When using this product

- **Do not use more than directed**
- Do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- Temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur.
- Use of this container by more than one person may spread infection.

Stop use and ask a doctor if symptoms persists.

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

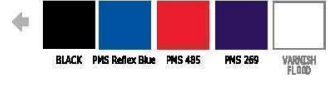
- Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- Children under 6 years of age: ask a doctor
- To spray, squeeze bottle quickly and firmly. Do not tilt head backwards while spraying. Wipe nozzle clean after use

Other information

- Store between 20° - 25° C (68° - 77° F)
- Retain carton for future reference on full labeling.

Inactive ingredients

Benzalkonium chloride, edetate disodium, glycerin, polyethylene glycol, povidone, propylene glycol, sodium phosphate dibasic, sodium phosphate monobasic, water



5728 SALERNO ROAD W
JACKSONVILLE, FL 32244
904•591•7100

MODIFIED: 02-18-08

SEALED WITH PRINTED NECKBAND
FOR YOUR PROTECTION

Do not use if safety seal around bottle is broken or missing

Drug Facts

Active ingredient	Purpose
Oxymetazoline hydrochloride, 0.05%	Nasal decongestant

Uses

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 - common cold
 - hay fever
 - sinusitis
 - upper respiratory allergies
- Shrinks swollen nasal membranes so you can breathe more freely.

Warnings

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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Drug Facts

(continued)

Other information

- Store between 20° to 25°C (68° to 77°F).
- Retain carton for future reference on full labeling.

Inactive ingredients

Benzalkonium Chloride, Edetate Disodium, Glycerin, Polyethylene Glycol, Povidone, Propylene Glycol, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Water

*This product is not manufactured or distributed by Schering-Plough HealthCare Products, owner of the registered trademark Afrin® Nasal Spray.

All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

Distributed by:
Kinray, Inc.
Whitestone, NY 11357

Manufactured by:
Lee Pharmaceuticals
Questions or Comments?
1-800-950-5337

LOT NO.

EXP.

Cat. No. 0767-000
#1517080 Rev 1/08



Nasal Spray

EXTRA MOISTURIZING
12 Hour Spray

Contains the Active Ingredient
Recommended Most by Pharmacists
and Physicians

Oxymetazoline
Hydrochloride 0.05%

Nasal Decongestant

- Moisturizes dry irritated noses
- Clears stuffy noses fast



1 fl. oz.
(30 mL)

*Compare to the
Active Ingredient in Afrin®
Extra Moisturizing Nasal Spray



Nasal Spray

EXTRA MOISTURIZING
12 Hour Spray

Contains the Active Ingredient
Recommended Most by Pharmacists
and Physicians

Oxymetazoline
Hydrochloride 0.05%

Nasal Decongestant



IP



PREFERRED PLUS 12 HOUR NASAL EXTRA MOISTURIZING

oxymetazoline hydrochloride spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:61715-047

Route of Administration NASAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	50.0 mg in 100.0 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM ANHYDRO US (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-047-02	1 in 1 CARTON		
1	NDC:61715-047-01	30 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/31/2008	

Labeler - Kinray (012574513)

Registrant - Lee Pharmaceuticals (056425432)

Establishment

Name	Address	ID/FEI	Business Operations
Kinray		012574513	label(61715-047)

Establishment

Name	Address	ID/FEI	Business Operations
Lee Pharmaceuticals		056425432	pack(61715-047)

Establishment

Name	Address	ID/FEI	Business Operations
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Samson Pharmaceuticals		088169581	manufacture(61715-047)
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Revised: 7/2013

Kinray