

OXYMETAZOLINE HCL- oxymetazoline hcl spray
KINGSTON PHARMA LLC

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.

NASAL SPRAY - ORIGINAL 15mL and 30mL

Active Ingredient: Oxymetazoline HCl 0.05%

Purpose: Nasal Decongestant

Uses

Temporarily relieves nasal congestion due to:

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

Ask a doctor before use if you have

- high blood pressure
- thyroid disease
- diabetes
- 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.

When using this product

- 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 persist. 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 right away.

Directions: Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostrill not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period. Children under six years of age: ask a doctor.

To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

Store between 20°C to 25°C (68° to 77° F)

benzalkonium chloride solution, edetate disodium, polyethylene glycol, povidone, propylene glycol, purified water, sodium phosphate monobasic, sodium phosphate dibasic

(pack: 30ml) Kingston NDC# 71027-013-02

(pack: 15ml) Kingston NDC# 71027-013-17

DO NOT USE IF SEAL OVER CAP IMPRINTED "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

Drug Facts

Active ingredient	Purpose
Oxymetazoline HCl 0.05%	Nasal Decongestant

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

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Ask a doctor before use if you have

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- diabetes trouble urinating due to an enlarged prostate gland.

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To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use. ▶

Drug Facts (cont.)

Other information
store between 20°C to 25°C (68°F to 77°F)
retain carton for future reference on full labeling.

Inactive ingredients
benzalkonium chloride solution, edetate disodium, polyethylene glycol, povidone, propylene glycol, purified water, sodium phosphate monobasic, sodium phosphate dibasic.

QUESTIONS AND COMMENTS?
+1 888-568-8511

ExcelMed Original acts in Effectively to provide relief from nasal congestion with no drowsiness

Distributed by:
Globe Pharma LLC.
West New York, NJ - USA 07093
www.globelpharma.com

12 HOUR NASAL SPRAY

COMPARE TO ACTIVE INGREDIENT IN Afrin®*

12 HOUR NASAL SPRAY

Oxymetazoline HCl Nasal Decongestant

Original
Fast Relief From Congestion

ExcelMed Original acts in Effectively to provide relief from nasal congestion with no drowsiness

0.5 OZ (15 mL)

12 HOUR NASAL SPRAY

COMPARE TO ACTIVE INGREDIENT IN Afrin®*

12 HOUR NASAL SPRAY

Oxymetazoline HCl Nasal Decongestant

Original
Fast Relief From Congestion

ExcelMed Original acts in Effectively to provide relief from nasal congestion with no drowsiness

*This product is not manufactured or distributed by Schering-Plough Healthcare Products Inc., distributors of Afrin Original 12 hour Nasal Spray

0.5 OZ (15 mL)

Lot: _____

Exp: _____

OXYMETAZOLINE HCL

oxymetazoline hcl spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71027-013
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71027-013-02	1 in 1 CARTON	03/01/2017	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:71027-013-17	1 in 1 CARTON	03/01/2017	
2		15 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 final	part341	03/01/2017	

Labeler - KINGSTON PHARMA LLC (080386521)**Registrant** - KINGSTON PHARMA LLC (080386521)**Establishment**

Name	Address	ID/FEI	Business Operations
KINGSTON PHARMA LLC		080386521	manufacture(71027-013)