OXYMETAZOLINE HCL- oxymetazoline hcl spray
PURINEPHARMA 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 membrances 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 rcur 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)

Retain carton for future reference on full labeling.

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

NDC 58599-027-01: 30 mL in a Bottle, NDC 58599-027-17: 15 mL in a Bottle


MediBest
12 HOUR
Nasal Spray
NASAL DECONGESTANT
ORIGINAL
Oxymetazoline HCl
1 FL. OZ. (30 mL)

SEE CARTON FOR FULL LABELING. Uses See carton.
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Warnings: **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. 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.

Active ingredient: Oxymetazoline HCl 0.05%
store between 20°C to 25° C (68°F to 77° F).

OXYMETAZOLINE HCL

oxymetazoline hcl spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58599-027
Route of Administration	ORAL, Type 0: Not a Combination Product		

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
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58599-027-01	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		
2	NDC:58599-027-17	1 in 1 CARTON		
2		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/09/2015	

Labeler - PURINEPHARMA LLC (019950491)

Registrant - PURINEPHARMA LLC (019950491)

Establishment

Name	Address	ID/FEI	Business Operations
PURINEPHARMA LLC		019950491	manufacture(58599-027)

Revised: 2/2015 PURINEPHARMA LLC