

OXYMETAZOLINE HCL- oxymetazoline hydrochloride spray
Padagis Israel Pharmaceuticals Ltd

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.

Perrigo Oxymetazoline HCl 0.05% Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask 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 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 (1-800-222-1222).

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 Use: Push firmly down on cap and turn counter clockwise. To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use. Secure cap after use.

Other information

- store at 20-25°C (68-77°F)
- retain carton for future reference on full labeling

Inactive ingredients

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

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Afrin[®] active ingredient

Oxymetazoline HCl 0.05%

Nasal Decongestant

Fast, Powerful Congestion Relief

For Colds & Allergies

Maximum Strength

12 Hour Relief

Spray Mist

1 FL OZ (30 mL)



OXYMETAZOLINE HCL

oxymetazoline hydrochloride spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:45802-410

Route of Administration	NASAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.05 g in 100 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			
	BENZYL ALCOHOL (UNII: LKG8494WBH)			
	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)			
	EDETATE DISODIUM (UNII: 7FLD91C86K)			
	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)			
	POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
	POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	WATER (UNII: 059QF0K00R)			
Product Characteristics				
Color	WHITE (Translucent)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-410-59	1 in 1 CARTON	12/05/2005	
1		30 mL in 1 BOTTLE, SPRAY; 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	12/05/2005		

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)