OXYMETAZOLINE HYDROCHLORIDE- oxymetazoline hydrochloride spray, metered
Zydus Pharmaceuticals (USA) 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.

Oxymetazoline Hydrochloride Concentrated Vapor Nasal Spray, 3/4 FL OZ (22 mL)

ACTIVE INGREDIENT

Oxymetazoline hydrochloride 0.05%

PURPOSE

Nasal decongestant

USES

- Temporarily relieves nasal congestion due to:

  ■ a cold ■ hay fever ■ upper respiratory allergies
- promotes nasal and sinus drainage
- temporarily relieves sinus congestion and pressure
- helps clear nasal passages; shrinks swollen membranes

WARNINGS

Ask a doctor before use if you have

■ heart disease ■ 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.

Directions

- **adults and children 6 to under 12 years of age (with adult supervision):**

2 or 3 sprays in each nostril not more 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.

Shake well before use. Before using the first time, remove the protective cap from the tip and prime metered pump by depressing firmly several times. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress pump all the way down with a firm even stroke and sniff deeply. Wipe nozzle clean after use.

Other information

- Store between 20º - 25ºC (68º - 77ºF)
- retain carton for future reference on full labeling

Inactive ingredients

benzalkonium chloride solution, camphor, edetate disodium, eucalyptol, glycin, menthol, polyethylene glycol, polysorbate 80, propylene glycol, purified water, sodium chloride, sodium hydroxide.

Manufactured by:

Cadila Healthcare Ltd.

Ahmedabad, India

Distributed by:

Zydus Pharmaceuticals USA Inc.

Pennington, NJ 08534

Rev.: 05/11

Revision Date: 05/31/2011

Container and Carton Labels

NDC 68382-418-07

Oxymetazoline Hydrochloride Concentrated Vapor Nasal Spray, ¾ FL OZ (22 mL)

Rx only

Zydus

DO NOT USE IF PRINTED SEAL OVER CAP IS TORN OR MISSING

Drug Facts

SEE CARTON FOR FULL LABELING

Active ingredient Oxymetazoline Hydrochloride 0.05%

Uses See Carton

Warnings: **Ask a doctor before use if you have**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

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- refer to carton for full label information

Distributed by : Zydus Pharmaceuticals USA Inc. Pennington, NJ 08534
Please visit www.zydususa.com or call 1-877-993-8779

Code No. GUJ/DRUG/1486 Rev. : 05/11

Lot :

Exp. :

Lot :
Exp :
Rev.: 05/11

UNVARNISHED AREA

Size : 70 x 35 x 134 mm
L W H

OXYMETAZOLINE HYDROCHLORIDE

oxymetazoline hydrochloride spray, metered

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68382-418
Route of Administration	NASAL		

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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EUCALYPTOL (UNII: RV6J6604TK)	
GLYCINE (UNII: TE7660XO1C)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
MENTHOL (UNII: L7T10EIP3A)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	

Product Characteristics

Color	WHITE (COLORLESS)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-418-07	1 in 1 CARTON		
1		22 mL in 1 INHALER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part341	09/24/2009	

Labeler - Zydus Pharmaceuticals (USA) Inc. (156861945)

Registrant - Zydus Pharmaceuticals (USA) Inc. (156861945)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	Analysis, Manufacture