

OXYMETAZOLINE HYDROCHLORIDE- oxymetazoline hydrochloride spray, metered
Dynamic Pharmaceuticals

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.

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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
- helps clear nasal passages
- shrinks swollen membranes
- temporarily relieves sinus congestion and pressure

Warnings

For nasal use only.

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 result
- 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 6-12 years of age (with adult supervision):** Pump 2 or 3 times in each nostril without tilting your head. Sniff deeply. Wipe nozzle clean after use.
- Do not use more often than once every 10 to 12 hours.
- Do not exceed 2 doses in any 24 hour period.
- **Children under 6 years of age:** consult a doctor

To use pump:

- Remove cap and safety clip.
- Hold with thumb at bottom of bottle and nozzle between fingers.
- Before using the first time, prime pump by depressing several times.

Other Information

- Retain carton for future reference on full labeling
- Remove lock ring before each use

Inactive Ingredients

aloe barbadensis gel, d-alpha-tocopherol-ester, disodium EDTA, disodium phosphate, ethylene & propylene oxide copolymer, eucalyptol, hydroxyethylcellulose, hydroxylated lecithin, menthol, monosodium phosphate, potassium sorbate, purified water

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 15 mL Carton

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Compare to the active
ingredient in Zicam[®]*

NEW!

Maximum

SINUS RELIEF

NO DRIP NASAL GEL

OXYMETAZOLINE HCl 0.05%

**Quickly relieves sinus
pressure & nasal congestion**

- **Long-lasting**
- **Non-drowsy**

12

Hour

Relief

Menthol Eucalyptus

0.5 FL OZ (15mL)



OXYMETAZOLINE HYDROCHLORIDE

oxymetazoline hydrochloride spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64762-864
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Oxymetazoline Hydrochloride (UNII: K89MJ0S5VY) (Oxymetazoline - UNII:8VLN5B44ZY)	Oxymetazoline Hydrochloride	0.2 mg in 0.4 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64762-864-15	1 in 1 CARTON		
1		15 mL in 1 BOTTLE, PUMP		
2	NDC:64762-864-22	1 in 1 CARTON		
2		22 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/04/2009	

Labeler - Dynamic Pharmaceuticals (617660712)

Establishment

Name	Address	ID/FEI	Business Operations
Dynamic Pharmaceuticals		617660712	MANUFACTURE

Revised: 12/2009

Dynamic Pharmaceuticals