

NASAL DECONGESTANT- oxymetazoline hydrochloride solution

H-E-B

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.

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
- sinusitis
- reduces swelling of nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose

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 exceed recommended dosage**
- **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 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 Pump

- shake well before use
- to open the cap, hold the bottle with one hand, use the other hand to press grooved area of cap firmly and turn counter clockwise
- line up the grooved line on the pump
- to spray, hold with thumb at bottom of the bottle and nozzle between fingers. Before using the first time, prime pump by depressing pump firmly several times.
- insert tip of nozzle into nostril. Pump 2 or 3 times into each nostril and sniff deeply without tilting head.
- wipe nozzle clean after each use
- to close the cap, turn until it 'clicks'

Other information

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

Inactive ingredients

benzalkonium chloride, benzyl alcohol, edetate disodium, polyethylene glycol, povidone, propylene glycol, purified water,

sodium phosphate dibasic, sodium phosphate monobasic

Questions or comments?

1-800-883-0085

PRINCIPAL DISPLAY PANEL -



NASAL DECONGESTANT

oxymetazoline hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-832
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 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-832-05	1 in 1 CARTON	06/15/2016	11/21/2016
1		15 mL in 1 BOTTLE, PUMP; 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	06/15/2016	

Labeler - H-E-B (007924756)

Revised: 9/2017

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