OXYMETAZOLINE HYDROCHLORIDE- oxymetazoline hydrochloride spray, metered
Rebel Distributors Corp

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 Decongestant Drug Facts

Active ingredient

Oxymetazoline HCl 0.05%

Purpose

Nasal decongestant

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center right away.

Uses

temporary relief of nasal congestion

° due to the common cold

° due to hay fever or other upper respiratory allergies

° associated with sinusitis

reduces swelling of nasal passages

temporarily restores freer breathing through the nose

Warnings

Do not exceed recommended dosage

This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge. The use of this container by more than one person may spread infection.

Do not use for more than 3 days.

Ask a doctor before use if you have:

° heart disease ° high blood pressure

° thyroid disease ° diabetes

° difficulty in urination due to enlargement of the prostate gland

When using this product, frequent or prolonged use may cause nasal congestion to recur or worsen.

Stop use and ask a doctor if symptoms persist.

If pregnant or breast-feeding, ask a health professional before use.

Directions

° **Adults and children 6 to under 12 years of age (with supervision):** 2 to 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

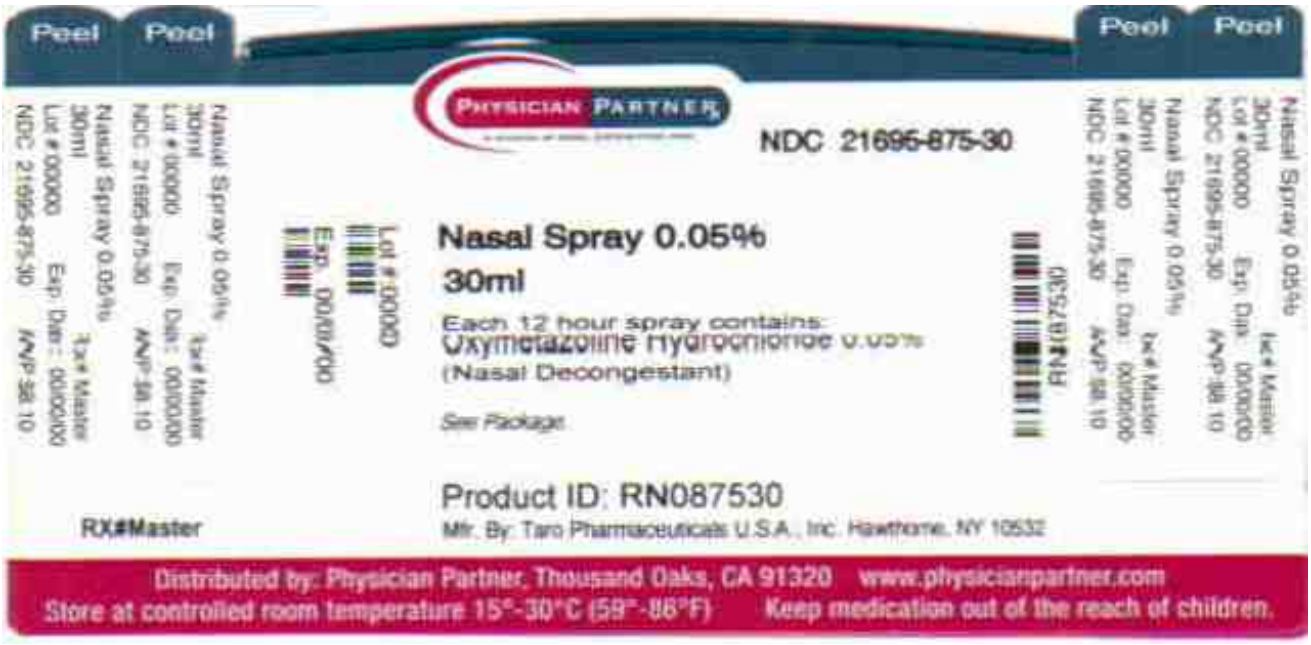
° **To spray:** squeeze the bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

Inactive ingredients

benzalkonium chloride, dibasic sodium phosphate (anhydrous), edetate disodium (dihydrate), monobasic sodium phosphate (monohydrate), polyethylene glycol 1450, povidone, propylene glycol, purified water.

Questions? Cal 1-866-923-4914

Package/Label Principal Display Panel



OXYMETAZOLINE HYDROCHLORIDE

oxymetazoline hydrochloride spray, metered

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21695-875(NDC:51672-2030)
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**

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC ANHYDROUS (UNII: 22ADO53M6F)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-875-15	15 mL in 1 BOTTLE, SPRAY		
2	NDC:21695-875-30	30 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/11/2008	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011 Rebel Distributors Corp