FAMILY CARE NASAL RELIEF - oxymetazoline hydrochloride spray United Exchange 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.

Drug Facts

Active ingredient Purpose

Oxymetazoline HCl 0.05%......Nasal Decongestant

Uses

- Temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- sinusitis
- shrinks swollen nasal membranes so you can breathe more freely

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 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 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.
- shake well before use. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use.
- children under 6 years of age: ask a doctor.

Other information

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

Inactive ingredients benzalkonium chloride, benzyl alcohol, dibasic sodium phosphate hydrate, disodium EDTA, distilled water, monobasic sodium phosphate dihydrate, PEG 1450, PVP K30

Distributed By:

United Exchange Corp

17211 Valley View Ave.

Cerritos, CA 90703 USA

Made in Korea



FAMILY CARE NASAL RELIEF

oxymetazoline hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:65923-551
Route of Administration	NASAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OXYMETAZOLINE HYDRO CHLO RIDE (OXYMETAZOLINE)	OXYMETAZOLINE HYDROCHLORIDE	0.05 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKONIUM CHLORIDE		
BENZYL ALCOHOL		
EDETATE DISO DIUM		
SO DIUM PHO SPHATE, MO NO BASIC, DIHYDRATE		
POLYETHYLENE GLYCOL 1450		
POVIDONE K30		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:65923-551-30	1 in 1 CARTON				
1		30 mL in 1 BOTTLE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	06/30/2013		

Labeler - United Exchange Corp (840130579)

Revised: 6/2013 United Exchange Corp