NASAL- oxymetazoline hydrochloride spray We Care Distributor 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.

We Care
12 Hour NASAL SPRAY
DECONGESTANT

Drug Facts

Active ingredient

Oxymetazoline Hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

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

Warnings

Ask a doctor before use if you have

- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to 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 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 within any 24-hour period
- **children under 6 years of age:** ask a doctor

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

Other information

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

Inactive ingredients

benzalkonium chloride, edetate disodium, polyethylene glycol, povidone, propylene glycol, purified water, sodium phosphate dibasic, sodium phosphate monobasic

Questions or Comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

PRINCIPAL DISPLAY PANEL - 15 mL Carton

WE CARE

12 Hour NASAL SPRAY DECONGESTANT

oxymetazoline hydrochloride 0.05%

Compare to active ingredient of Afrin



oxymetazoline hydrochloride spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-038	
Route of Administration	NASAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89 MJ0 S5VY) (OXYMETAZOLINE - UNII:8 VLN5B44ZY)	O XYMETAZOLINE HYDRO CHLO RIDE	5 g in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)		
EDETATE SO DIUM (UNII: MP1J8420 LU)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SO DIUM PHO SPHATE, MO NO BASIC (UNII: 3980 JIH2SW)		
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)		
PO VIDO NE (UNII: FZ989GH94E)		
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:70005-038- 01	1 in 1 CARTON	08/23/2016		
1	15 mL in 1 BOTTLE, SPRAY; 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	08/23/2016		

Labeler - We Care Distributor Inc. (079832998)

Establishment				
Name	Address	ID/FEI	Business Operations	
PURINE PHARMA LLC		019950491	manufacture(70005-038)	

Revised: 8/2016 We Care Distributor Inc.