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.

Family Care Nasal Spray Original 0.5 oz NBE Afrin Nasal Spray Original 570 (2018) ZDP

Active ingredient

Purpose

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

Uses

- temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- shrinks swollen nasal membranes so you can breathe more freely
- temporarily relieves sinus congestion and pressure

Warnings

Ask a doctor before use if you have

- Theart 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 (1-800-222-1222) 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: consult a doctor. Shake well before use. Remove safety seal. To
 open, rotate cap to align the marks. Squeeze cap on both sides in a counter-clockwise turn and pull
 off to remove. To spray, remove clamp and hold bottle with thumb at base and nozzle between first
 and second fingers. Without tilting the head, insert nozzle into nostril. Fully depress rim with a firm,
 even stroke and sniff deeply. Wipe nozzle clean after use and snap cap back onto bottle.

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, edetate disodium, polyethylene glycol 1500, povidone k30, purified water, sodium phosphate dibasic, sodium phosphate monobasic Monohydrate

Distributed By:

United Exchange Corp Cypress, CA 90630 USA 1-888-645-8204 Made in China



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oxymetazoline hydrochloride spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:65923-570

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE -	OXYMETAZOLINE	0.05 g			
UNII:8 VLN5B44ZY)	HYDROCHLORIDE	in 100 mL			

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
BENZO DO DECINIUM CHLO RIDE (UNII: Y5A751G47H)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)				
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)				
PO VIDO NE K30 (UNII: U725QWY32X)				
SO DIUM PHO SPHATE, MO NO BASIC, MO NO HYDRATE (UNII: 593YOG76RN)				
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO 53M6 F)				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:65923-570- 15	1 in 1 CARTON	05/21/2018			
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	06/30/2013			

Labeler - United Exchange Corp (840130579)

Revised: 12/2019 United Exchange Corp