OXYMETHAZOLINE HCL- oxymethazoline hcl spray
NuCare Pharmaceuticals,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.

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12 Hour Decongestant Nasal Spray

Drug Facts

Active ingredient

Oxymetazoline HCL 0.05%

Purpose

Nasal decongestant

Uses

temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies

temporarily relieves sinus congestion and pressure

shrinks swollen nasal membranes

Ask a doctor before use if you have

heart disease

high blood pressure

thyroid disease

diabetes

trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if symptoms presist

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 10-12 hours. Do not exceed 2 doeses in 24 hours.

children under 6 years of age: ask a doctor.

Instructions for use: Shake well before use. to open, rotate cap to align the marks. Squeeze cap on toh sides in a counter-clockwise turn and pull to remove. To spray, hold bottles 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 20º to 25º C (68º to 77º F)

retain carton for future referance on full labeling

Inactive ingredients

benzalkoium cjloride, dibasic sodium phosphate, edetate disodium dihydrate, monobasic sodium phosphate, polyethylene glycol, propylene glycol, povidone, purified water

Questions or comments?

call **516-341-0666,** 8:30 am - 4:30 pm ET, Monday - Friday

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

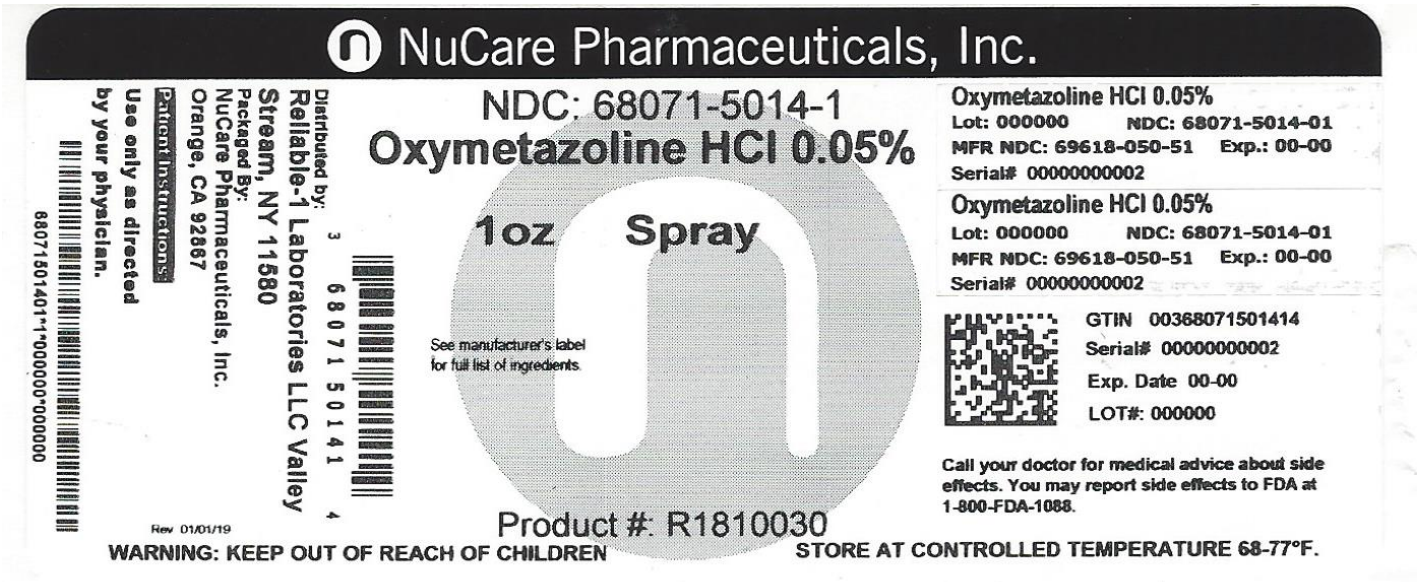
When using this prduct

do not use more than directed

do not use 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, sneexing, or an increased nasal discharge may occur

use of this container by more than one person may spread infection



OXYMETHAZOLINE HCL

oxymethazoline hcl spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-5014(NDC:69618-050)
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

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
POVIDONE (UNII: FZ989GH94E)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68071-5014-1	1 in 1 BOX; Type 0: Not a Combination Product	08/05/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2019	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-5014)

Revised: 2/2021 NuCare Pharmaceuticals,Inc.