LEADER ORIGINAL NASAL- oxymetazoline hydrochloride spray
Cardinal Health

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.

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

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 more than 3 days. Use only as directed. Frequesnt 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 hep 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.
- children under 6 years of age: ask a doctor.
- shake well before use. To open, rotate cap to align the marks. Squeeze cap on both sides in a counterclockwise 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 the 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, dibasic sodium phosphate hydrate, disodium EDTA, distilled water, monobasic sodium phosphate dihydrate, PEG 1450, PVP K30

Distributed By:

Cardinal Health

Dublin, Ohio 43017

Made in Korea

LEADER ORIGINAL NASAL

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49781-041
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 in 100 mg

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
POVIDONE K30 (UNII: U725QWY32X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-041-01	1 in 1 CARTON	11/07/2016	
1		30 mg 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	08/29/2013	

Labeler - Cardinal Health (097537435)

Revised: 11/2016 Cardinal Health