LEADER ORIGINAL NASAL - oxymetazoline hydrocholoride 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.

Drug Facts

Active Ingredient Purpose

Oxymetazoline hydrochloride 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 external 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 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 often 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.
- 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.

Other information

- store between 15º and 25ºC (59º and 77ºF)

- retain carton for future reference on full labeling

Inactive ingredients: benzalkonium chloride solution, edetate disodium, polyethylene glycol, sodium phosphate dibasic, sodium phosphate monobasic, water

DISTRIBUTED BY CARDINAL HEALTH

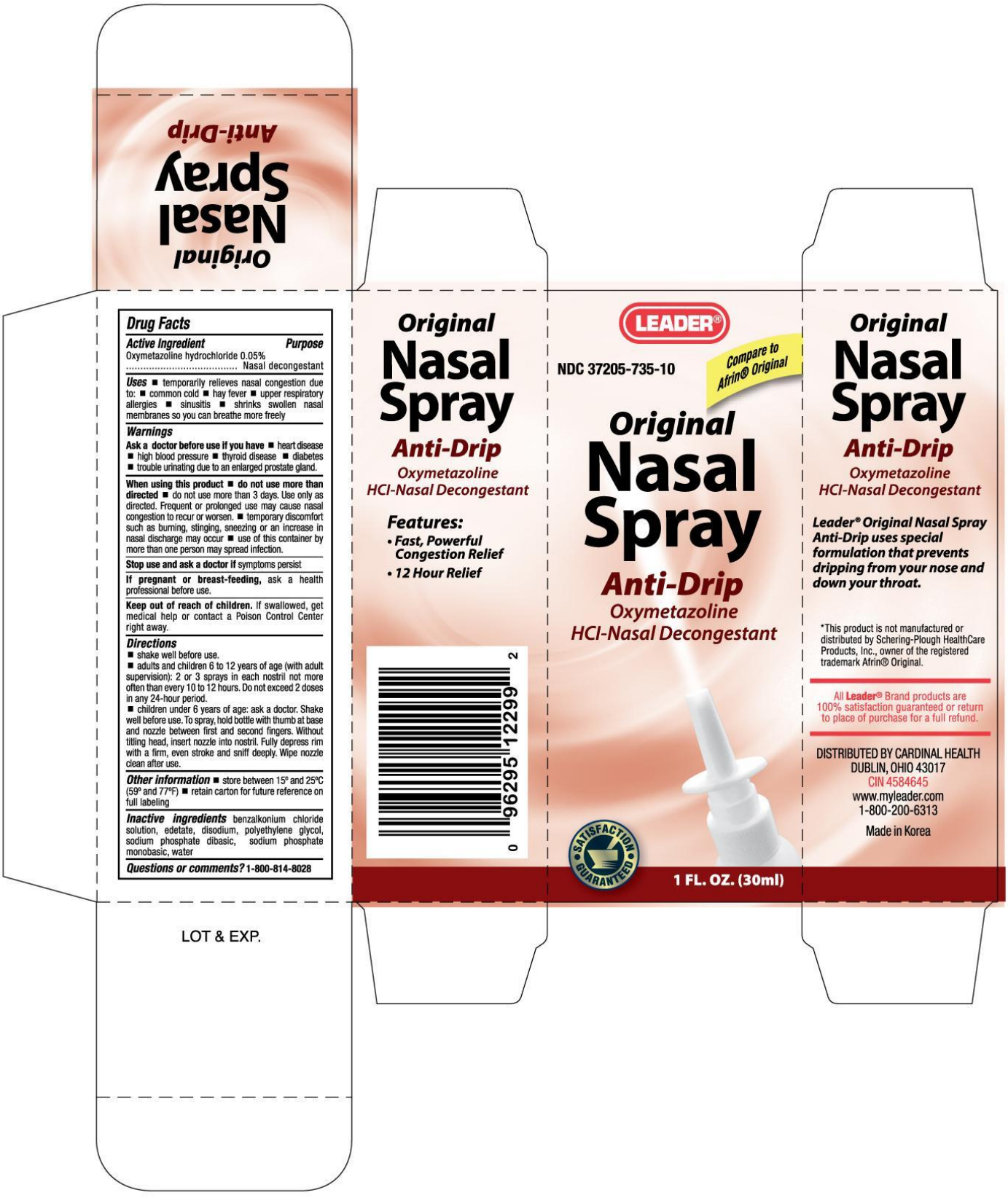
DUBLIN, OHIO 43017

CIN 4584645

www.myleader.com

1-800-200-6313

Made in Korea



LEADER ORIGINAL NASAL

oxymetazoline hydrocholoride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-735

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 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-735-10	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	09/30/2012	

Labeler - CARDINAL HEALTH (097537435)

Revised: 9/2012 CARDINAL HEALTH