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 15° and 25°C (59° and 77°F)

• 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

Anti-Drip Spray Original

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

Ask a doctor before use if you have ■ heart disease
■ high blood pressure ■ thyroid disease ■ diabetee
■ 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

shake well before use.

- shake well before use.

 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. Shake well before use. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without titling head, insert nozzle into nostril. Fully depress rim with a firm pen extrake and engif depelv Micro prozzle. with a firm, even stroke and sniff deeply. Wipe nozzle

Other information ■ store between 15° and 25°C (59° and 77°F) ■ retain carton for future reference on full labeling

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

Questions or comments? 1-800-814-8028

LOT & EXP.

Original **Nasal Spray**

Oxymetazoline **HCI-Nasal Decongestant**

Features:

- · Fast, Powerful Congestion Relief
- 12 Hour Relief



LEADER

NDC 37205-735-10



Original Nasal Spray

Anti-Drip Oxymetazoline **HCI-Nasal Decongestant**

1 FL. OZ. (30ml)

Original Nasa

Oxymetazoline **HCI-Nasal Decongestant**

Leader® Original Nasal Spray Anti-Drip uses special formulation that prevents dripping from your nose and down your throat.

*This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., owner of the registered trademark Afrin® Original.

All **Leader®** Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017

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

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE -	OXYMETAZOLINE	0.05 g				
IINII:8VI N5R447V)	HVDROCHLORIDE	in 100 mI				

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
SODIUM PHO SPHATE (UNII: SE337SVY37)			
WATER (UNII: 059QF0KO0R)			

P	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