

NASAL DECONGESTANT PREMIER VALUE- oxymetazoline hcl 0.05% spray
Chain Drug Consortium

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.

Nasal Spray

Active Ingredient

Oxymetazoline hydrochloride 0.05%

□ Purpose

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

□ Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- diabetes
- thyroid disease
- 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 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 within any 24-hour period.
- **Children under 6 years of age:** Ask a doctor.

Shake well before use. Before using for the first time remove the protective cap from the tip and prime metered pump by depressing pump firmly several times. 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 each use.

Other Information

- store between 20°-25°C (68°-77°F)
- retain carton for future reference on full labeling

Inactive Ingredients

Benzalkonium Chloride, Edetate Disodium, Polyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic.

Additional information listed on other panels

SAFETY SEALED: DO NOT USE IF IMPRINTED SEAL ON BOTTLE IS BROKEN OR MISSING.

*This product is not manufactured or distributed by MSD Consumer Care, INC., distributor of Afrin.

Distributed By:

Chain Drug Consortium

3301 NW Boca Raton Blvd, Suite 101

Boca Raton, FL 33431

Made in USA

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

Principal Display

*Compare to the active ingredient in Afrin Original Nasal Spray

Premier Value

Nasal Decongestant

Sinus Nasal Spray

Oxymetazoline HCl 0.05%

REGULAR STRENGTH

Fast, Powerful Congestion Relief

- Colds

- Allergies

1 FL OZ (30 mL)

Nasal Decongestant
Nasal Spray
Oxymetazoline HCl 0.05%

Premier Value

COMPARE TO THE ACTIVE INGREDIENT IN AFIRIN® ORIGINAL NASAL SPRAY

Drug Facts	Purpose
Active ingredient Oxymetazoline hydrochloride 0.05%.....	Nasal decongestant
Uses	
<ul style="list-style-type: none"> • Temporarily relieves nasal congestion due to: <ul style="list-style-type: none"> • Common cold • Hay fever • Upper respiratory allergies • Shrinks swollen nasal membranes so you can breathe more freely 	
Warnings	
<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> • heart disease • diabetes • trouble urinating due to enlarged prostate gland. • high blood pressure • thyroid disease 	
When using this product	
<ul style="list-style-type: none"> • 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 	
<p>Stop use and ask a doctor if symptoms persist.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<ul style="list-style-type: none"> • 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 within any 24-hour period. • Children under 6 years of age: Ask a doctor. <p>Shake well before use. Before using for the first time remove the protective cap from the tip and prime metered pump by depressing pump firmly several times. 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.</p>	
Other Information	
<ul style="list-style-type: none"> • store between 20°-25°C (68°-77°F) • retain carton for future reference on full labeling 	
Inactive ingredients Benzalkonium Chloride, Edetate Disodium, Polyethylene Glycol,	

Drug Facts
(continued)

Povidone, Propylene Glycol, Purified Water, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic.

SAFETY SEALER: DO NOT USE IF IMPRINTED SEAL ON BOTTLE IS BROKEN OR MISSING

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CHAIN DRUG CONSORTIUM
3301 NW BOCA RATON BLVD
SUITE 101 BOCA RATON, FL 33431
MADE IN USA

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NDC 68016-316-03

Premier Value

Nasal Decongestant

Nasal Spray

Oxymetazoline HCl 0.05%

REGULAR STRENGTH

Fast, Powerful
Congestion Relief

Colds • Allergies

1 FL OZ (30 mL)

8 40986 01516 8

COMPARE TO THE ACTIVE INGREDIENT IN AFIRIN® ORIGINAL NASAL SPRAY

Premier Value

Nasal Decongestant

Nasal Spray

Oxymetazoline HCl 0.05%

REGULAR STRENGTH

Fast, Powerful
Congestion Relief

Colds • Allergies

1 FL OZ (30 mL)



Nasal Decongestant

Nasal Spray

Oxymetazoline HCl 0.05%

REGULAR STRENGTH

Safety Sealed: Do not use if imprinted seal on bottle is broken or missing

1 FL OZ (30 mL)

SEE CARTON FOR FULL LABELING.

Uses: See Carton.

Directions: 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.

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 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 right away.

Active ingredient: Oxymetazoline hydrochloride 0.05%
Store at 20°-25°C (68°-77°F).

DISTRIBUTED BY CHAIN DRUG CONSORTIUM
3301 NW BOCA RATON BLVD
SUITE 101 BOCA RATON, FL 33431 MADE IN USA

NASAL DECONGESTANT PREMIER VALUE

oxymetazoline hcl 0.05% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-316
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 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-316-03	1 in 1 CARTON		
1		30 mL 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	11/04/2014	

Labeler - Chain Drug Consortium (101668460)**Registrant** - Product Quest Mfg (927768135)**Establishment**

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(68016-316)

Revised: 10/2015

Chain Drug Consortium