

## **NASAL DECONGESTANT EXTRA MOISTURIZING PREMIER VALUE- 0.05%**

### **oxymetazoline hcl 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.*

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### **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, Benzyl Alcohol, Edetate Disodium, Flavor, Glycerin, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Sodium Carboxymethyl Cellulose, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Water.

### **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 Extra Moisturizing.

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 Extra Moisturizing

### **Premier Value**

Nasal Decongestant

**Extra Moisturizing Nasal Spray**

Oxymetazoline HCl 0.05%

Fast, Powerful Congestion Relief

- Colds
- Allergies

Helps Rehydrate

Dry Nasal Passages

1 FL OZ (30 mL)



Oxymetazoline HCl 0.05%  
**Extra Moisturizing Nasal Spray**  
 Nasal Decongestant  
 Premier Value  
 EXTRA MOISTURIZING  
 INGREDIENT IN AFRIN®  
 COMPARE TO THE ACTIVE

**Drug Facts**

Active ingredient	Purpose
Oxymetazoline hydrochloride 0.05%.....	Nasal decongestant

**Uses**

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  - 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
- diabetes
- trouble urinating due to enlarged prostate gland.
- high blood pressure
- thyroid disease

When using this product

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**Inactive ingredients** Benzalkonium Chloride, Benzyl Alcohol, Edetate Disodium, Flavor, Glycerin, ▶

**Drug Facts (continued)**

Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Sodium Carboxymethyl Cellulose, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Water.

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 CEAIN 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.

NDC 68016-304-03  
 COMPARE TO THE ACTIVE INGREDIENT IN AFRIN® EXTRA MOISTURIZING  
 Premier Value®

Nasal Decongestant  
**Extra Moisturizing Nasal Spray**

Oxymetazoline HCl 0.05%

Fast, Powerful Congestion Relief  
 Colds • Allergies  
 Helps Rehydrate Dry Nasal Passages



1 FL OZ (30 mL)

COMPARE TO THE ACTIVE INGREDIENT IN AFRIN® EXTRA MOISTURIZING  
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Nasal Decongestant  
**Extra Moisturizing Nasal Spray**  
 Oxymetazoline HCl 0.05%

Fast, Powerful Congestion Relief  
 Colds • Allergies  
 Helps Rehydrate Dry Nasal Passages

1 FL OZ (30 mL)



8 40986 01518 2



Nasal Decongestant

# Extra Moisturizing Nasal Spray

Oxymetazoline HCl 0.05%

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 EXTRA MOISTURIZING PREMIER VALUE

0.05% oxymetazoline hcl spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-304
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)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-304-03	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(68016-304)

Revised: 10/2015

Chain Drug Consortium