

DRISTAN 12 HR- oxymetazoline hydrochloride spray

Foundation Consumer Brands

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.

Dristan®
12 hr

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to a cold, hay fever or other upper respiratory allergies
- shrinks swollen membranes
- temporarily restores freer breathing through the nose
- temporarily relieves sinus congestion and pressure

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
- may cause temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge
- the 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 under 12 years of age (with adult supervision): 2 to 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, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use. Replace cap tightly to maintain child resistant closure.

Other information

- store at 20-25°C (68-77°F)
- container is filled to proper level for correct spray action
- retain carton for full labeling

Inactive ingredients

benzalkonium chloride, benzyl alcohol, dibasic sodium phosphate, edetate disodium, hypromellose, phosphoric acid, purified water, sodium chloride

Questions or comments?

Call **1-888-594-0710** weekdays 9 AM to 5 PM EST

Distributed by:
Foundation Consumer Brands, LLC
Pittsburgh, PA 15212

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

Dristan®
12
HOUR
NASAL
SPRAY

Oxymetazoline HCl 0.05%
Nasal Decongestant

Fast Acting Relief
Sinus & Nasal
Congestion

Relieves:

- ✓ Sinus Congestion & Pressure

- ✓ Nasal Congestion due to Colds & Allergies
- ✓ Swelling of Nasal Passages

0.5 FL OZ (15 mL)



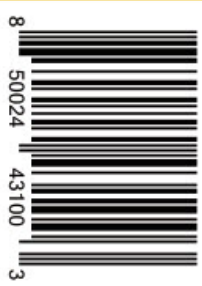
Drug Facts (continued)

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Distributed by:
Foundation Consumer Brands, LLC
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Made in Canada
dristan.com

Do Not Use if seal imprinted with "Dristan" on bottle neck is broken or missing.



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12 HOUR NASAL SPRAY
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Oxymetazoline HCl 0.05%
Nasal Decongestant
Fast Acting Relief
Sinus & Nasal Congestion



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Dristan® 12 HOUR NASAL SPRAY

850B130

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121120

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80070-400
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics

Color	YELLOW (clear, colorless to slightly yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80070-400-05	1 in 1 CARTON	08/17/2021	
1		15 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	08/17/2021	

Revised: 8/2021

Foundation Consumer Brands