

DRISTAN 12 HR- oxymetazoline hydrochloride spray
Foundation Consumer Brands

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)



DRISTAN 12 HR 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		
2	NDC:80070-400-15	45 mL in 1 CARTON; Type 0: Not a Combination Product	11/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/17/2021	

Labeler - Foundation Consumer Brands (117603632)