AFRIN SEVERE CONGESTION- oxymetazoline hydrochloride spray Bayer HealthCare LLC.

Afrin ®

Severe Congestion

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
 - o common cold
 - hay fever
 - upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- 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
- 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.

Directions

- adults and children 6 to under 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, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

Other information

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

Inactive ingredients

benzalkonium chloride solution, benzyl alcohol, camphor, edetate disodium, eucalyptol, menthol, polysorbate 80, propylene glycol, purified water, sodium phosphate dibasic, sodium phosphate monobasic

Questions or comments?

Questions or comments? 1-800-317-2165

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton



Afrin®

Oxymetazoline HCl Nasal Solution-Nasal Decongestant

Severe Congestion

NASAL SPRAY

Fast, Powerful Congestion Relief

Colds • Allergies

up to 12 Hour Relief

Maximum Strength

#1 Doctor & Pharmacist Recommended Nasal Brand

BAYER

1/2 FL OZ (15 mL)

AFRIN SEVERE CONGESTION

oxymetazoline hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-7020
Route of Administration	NASAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZ OLINE HYDROCHLORIDE	0.05 g in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
EUCALYPTOL (UNII: RV6J6604TK)		
MENTHOL (UNII: L7T10EIP3A)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)		
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:11523- 7020-1	1 in 1 CARTON	08/31/2000	
1	15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	08/31/2000	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2023 Bayer HealthCare LLC.