

CHILDREN AFRIN EXTRA MOISTURIZING STUFFY NOSE PUMP MIST STUFFY NOSE PUMP MIST- oxymetazoline hydrochloride spray, metered Bayer HealthCare LLC.

Children's Afrin[®] Extra Moisturizing Stuffy Nose Pump Mist
Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.025%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
 - 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 or a child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- children 2 to under 6 years of age (with adult supervision): 2 or

3 sprays in each nostril not more often than every 10 to 12 hours. **Use only recommended amount. Do not exceed 2 doses in any 24-hour period.**

- children under 2 years of age: consult a doctor

To Use: Shake well before use. Hold white tabs, press grooved area of cap firmly and turn counter clockwise. Before using the first time, prime metered pump by depressing pump firmly up to 10 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. Wipe nozzle clean after use. Secure cap 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, dibasic sodium phosphate, edetate disodium, glycerin, monobasic sodium phosphate, polyethylene glycol, povidone, propylene glycol, purified water

Questions or comments?

Call 1-800-317-2165

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton



Oxymetazoline HCl Nasal Solution-Nasal Decongestant

Children's Afrin®

No Drip EXtra Moisturizing Stuffy Nose Pump Mist

CHILDREN AFRIN EXTRA MOISTURIZING STUFFY NOSE PUMP MIST

oxymetazoline hydrochloride spray, metered

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11523-0091

Route of Administration NASAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.025 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KOOR)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-0091-1	1 in 1 CARTON	07/14/2022	
1		15 mL in 1 BOTTLE, PUMP; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:11523-0091-2	2 in 1 CARTON	12/02/2022	
2		15 mL in 1 BOTTLE, PUMP; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/03/2022	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2023

Bayer HealthCare LLC.