THERAFLU SEVERE CONGESTION RELIEF NASAL MIST- oxymetazoline hcl spray
Haleon US Holdings LLC

Drug Facts

Active ingredient

Oxymetazoline HCl 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal decongestion due to:
    - common cold
    - hay fever or other upper respiratory allergies (allergic rhinitis)
- temporarily relieves stuffy nose
- helps clear nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose
- helps decongest sinus openings and passages; 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 exceed recommended dosage**
- do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor.
- temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may occur
- 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

- **do not use more than directed**
- **adults and children 6 years to under 12 years of age (with adult supervision):** 2 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:** consult a doctor

To Use: Shake well before use. To remove the cap, press grooves on each side and turn to lift cap. Before using the first time, prime the sprayer by pressing the button several times. To spray, insert sprayer tip into nostril, firmly press the button with thumb and sniff deeply. Stay upright while spraying. Wipe sprayer tip clean and secure cap after use.

Other information

- do not store above 25°C (77°F)

Inactive ingredients

benzalkonium chloride solution, edetate disodium, purified water, sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic, sorbitol

Questions?

1-855-328-5259

Additional Information

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE. KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

Breathe Better at the **Push** of a **Button**

Find grooves on each side of cap

Press grooves and turn to lift cap

Press firmly with thumb

Do not use if red unlock icon is seen on either end of the carton before first opening or if the red unlock icon is absent after opening.

* vs. the leading nasal mist

Package/Label Principal Display Panel

NEW

THERAFLU

SEVERE

CONGESTION RELIEF

NASAL MIST

Oxymetazoline HCl –

Nasal Decongestant

12 HR RELIEF

UNBLOCKS IN SECONDS

Comfortable to use

- **One-thumb push of a button**
- **Shorter nozzle***
- **Ultra fine mist**

0.34 FL OZ (10 mL)

THERAFLU SEVERE CONGESTION RELIEF NASAL MIST

oxymetazoline hcl spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-0110
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0110-01	1 in 1 CARTON	06/01/2025	
1		10 mL in 1 BOTTLE, SPRAY; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2025	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2025 Haleon US Holdings LLC