

12 HOUR NASAL DECONGESTANT EXTRA MOISTURIZING- nasal spray liquid WinCo Foods LLC

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.

Winco 12 Hour Nasal Spray Extra Moisturizing

Drug Facts

Active Ingredient

Oxymetazoline Hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- sinusitis
- upper respiratory allergies
- Shrink swollen membranes so you can breathe more freely

Warnings

Ask a Doctor before use if you have

- heart disease
- high blood pressure
- diabetes
- thyroid disease
- trouble urinating due to enlarged prostate gland.

When using this product

- **Do not use more than directed**
- do not use for more than three 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.

ask a health professional before use.

Keep out of the reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

- Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more 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 spray, squeeze bottle quickly and firmly. Do not tilt head backwards while spraying, wipe nozzle clean after use.

Other information

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

Inactive Ingredients:

benzalkonium chloride, edetate disodium, glycerin, polyethylene glycol, povidone, propylene glycol, sodium phosphate dibasic, sodium phosphate monobasic, water

Principal display panel- Carton

WinCo Foods

Extra Moisturizing Nasal Spray

Oxymetazoline HCL 0.05%

Fast Powerful relief of Nasal congestion

12 Hour Relief

1 FL OZ (30ml)



Principal display panel- Bottle back label

SEE CARTON FOR FULL LABELING.

USES: See carton.

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.

Active Ingredient: Oxymetazoline hydrochloride, 0.05%

Store between 20° to 25°C (68° to 77°F)

Questions? Call 800-824-1706 Monday - Friday 9am - 4pm MST

* This product is not manufactured or distributed by BAYER, WF2009
owner of the registered trademark AFRIN® Extra Moisturizing. 7002351

Principal display panel -Bottle label Front

WinCo Foods

Extra Moisturizing Nasal Spray

Oxymetazoline HCL 0.05%

Fast Powerful Relief of Nasal congestion

12 Hour Relief

1 FL OZ (30ml)

*Compare to active ingredient in
AFRIN® Extra Moisturizing

WinCo
FOODS

EXTRA MOISTURIZING
Nasal Spray

Spray Mist

OXYMETAZOLINE HCl
NASAL DECONGESTANT

Fast, Powerful Relief
from Nasal Congestion

•••••

12 Hour Relief

1 FL OZ (30 mL)

7002350

12 HOUR NASAL DECONGESTANT EXTRA MOISTURIZING

nasal spray liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-377
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	50 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
GLYCERIN (UNII: PDC6A3C0OX)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
POVIDONE K29/32 (UNII: 390RMW2PEQ)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-377-08	1 in 1 CARTON	03/25/2021	
1		30 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	03/25/2021	

Labeler - WinCo Foods LLC (056098817)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Revised: 1/2022

WinCo Foods LLC