

AFRIN- oxymetazoline hydrochloride spray
Navajo Manufacturing Company Inc.

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.

Afrin

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

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 have

• heart disease • high blood pressure • diabetes • thyroid disease • 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 card for future reference on full labeling
- **SAFETY SEALED:** Do not use if "Afrin® Security Seal" imprinted on bottle is broken or missing

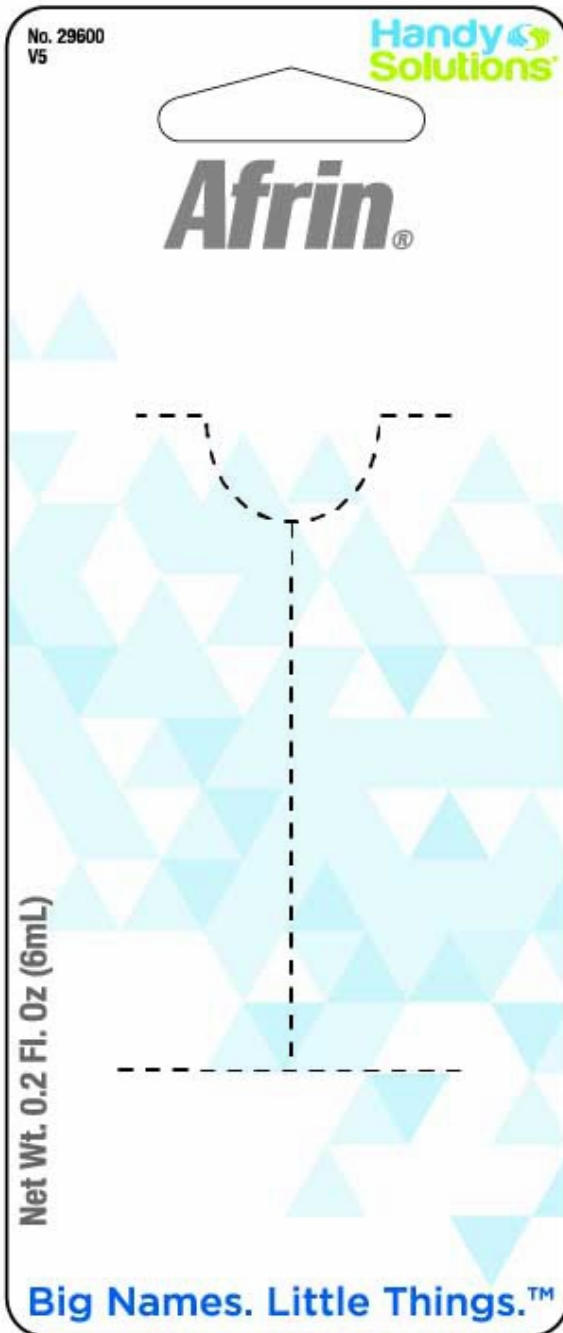
Inactive ingredients

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

☐ Questions

Call 1-800-317-2165, M-F 8am-5pm

Package Labeling:



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Afrin.
Original

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Other information	
<ul style="list-style-type: none"> store between 20° to 25°C (68° to 77°F) retain card for future reference on full labeling SAFETY SEALED: Do not use if seal imprinted "Afrin® Security Seal" is broken or missing. 	
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Questions Call 1-800-317-2165, M-F 8am-5pm	

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AFRIN

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-185(NDC:11523-1167)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-185-01	15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/04/2017	

Labeler - Navajo Manufacturing Company Inc. (091917799)**Establishment**

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-185)

Revised: 3/2023

Navajo Manufacturing Company Inc.