

**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.*

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**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:**

No. 29600  
V5

Handy Solutions®

**Afrin®**

Net Wt. 0.2 Fl. Oz (6mL)

**Big Names. Little Things.™**

No. 29600  
V5

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Nos. 6,824,762 and 6,316,483

**Afrin.  
Original**

<b>Drug Facts</b>	
<b>Active ingredient</b> Oxymetazoline hydrochloride 0.05% . . . . .	<b>Purpose</b> Nasal decongestant
<b>Uses</b>	
<ul style="list-style-type: none"> <li>temporarily relieves nasal congestion due to:               <ul style="list-style-type: none"> <li>common cold</li> <li>hay fever</li> <li>upper respiratory allergies</li> </ul> </li> <li>temporarily relieves sinus congestion and pressure</li> <li>shrinks swollen nasal membranes so you can breathe more freely</li> </ul>	
<b>Warnings</b>	
<b>Ask a doctor before use if you have</b> <ul style="list-style-type: none"> <li>heart disease</li> <li>high blood pressure</li> <li>diabetes</li> <li>thyroid disease</li> <li>trouble urinating due to an enlarged prostate gland</li> </ul>	
<b>When using this product</b> <ul style="list-style-type: none"> <li>do not use more than directed</li> <li>do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> <li>temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur</li> <li>use of this container by more than one person may spread infection</li> </ul>	
<b>Stop use and ask a doctor if symptoms persist</b> If pregnant or breast-feeding, ask a health professional before use. <b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>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.</li> <li>children under 6 years of age: ask a doctor.</li> </ul> <b>To Use:</b> Push firmly down on cap and turn counter clockwise. To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use. Secure cap after use.	
<b>Other information</b> • store between 20° to 25°C (68° to 77°F) • retain card for future reference on full labeling • <b>SAFETY SEALED:</b> Do not use if seal imprinted "Afrin® Security Seal" is broken or missing.	
<b>Inactive ingredients</b> benzalkonium chloride solution, edetate disodium, polyethylene glycol, povidone, propylene glycol, purified water, sodium phosphate dibasic, sodium phosphate monobasic	
<b>Questions</b> Call 1-800-317-2165, M-F 8am-5pm	

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0 24291 29600 3  
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**AFRIN**

oxymetazoline hydrochloride spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67751-185(NDC:11523-1167)
<b>Route of Administration</b>	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: 12/2019

Navajo Manufacturing Company Inc.