

**12 HOUR ORIGINAL NASAL DECONGESTANT- nasal spray liquid**  
**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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**Dr. Sheffield's Original 12 Hour Relief Nasal Spray**

***Active Ingredient***

Oxymetazoline HCl 0.05%

***Purpose***

Nasal Decongestant

***Uses***

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- sinusitis
- upper respiratory allergies

Shrinks 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.**

**If pregnant or breast-feeding, 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.

***Directions***

- 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.

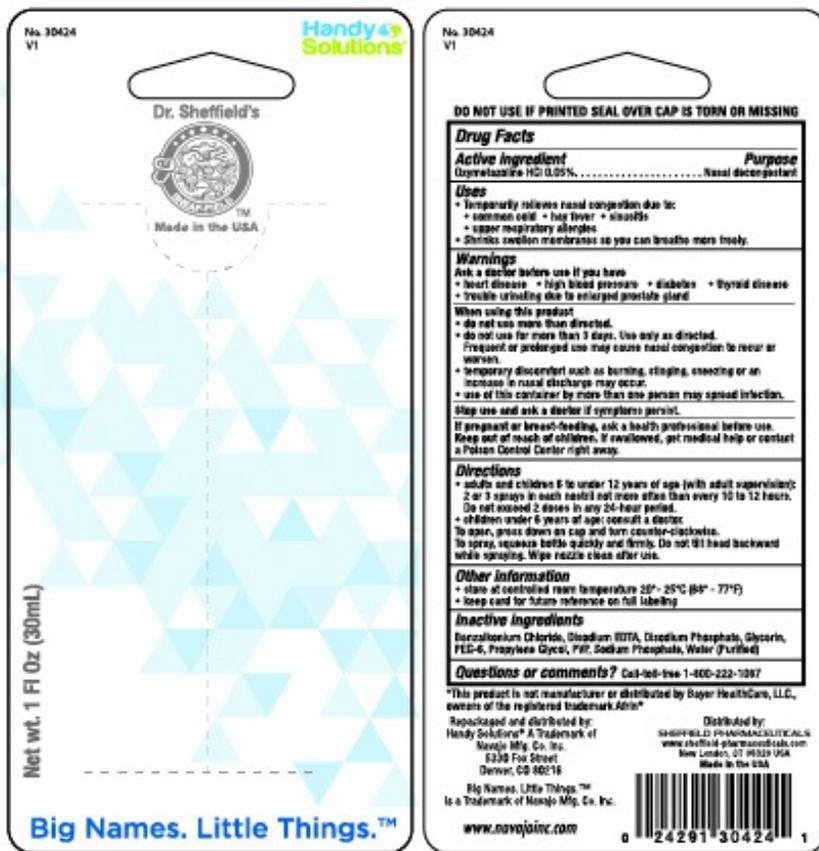
**Other information**

- store at a controlled room temperature 20°-25°C (68°-77°F)
- keep card for future reference on full labeling

**Inactive ingredients**

Benzalkonium Chloride, Disodium EDTA, Disodium Phosphate, Glycerin, PEG-6, Propylene Glycol, PVP, Sodium Phosphate, Water (Purified)

**Principal Display Panel**



12 HOUR ORIGINAL NASAL DECONGESTANT			
nasal spray liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-209(NDC:11527-140)
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: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-209-01	1 in 1 PACKAGE	12/10/2020	
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	12/10/2020	

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

**Registrant** - Navajo Manufacturing Company Inc. (136941411)

### Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-209) , repack(67751-209)

### Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(67751-209)