

## **FAMILY WELLNESS OXYMETAZOLINE SINUS SEVERE- oxymetazoline spray FAMILY DOLLAR (Family Wellness)**

*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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### **Family Wellness Nasal Spray Sinus Severe**

#### **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 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.
- Before using for the first time, remove the protective cap from the tip and prime the pump by depressing pump firmly several times. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress rim with a firm and even stroke, and sniff deeply. 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, Benzyl Alcohol, Citric Acid Anhydrous, Disodium EDTA, Fragrance, Polysorbate 80, Sodium Citrate, Sorbitol, Water (Purified)

**Principal Display Panel- Bottle**

Family Wellness                      NDC 55319-827-30

Severe Nasal Spray

Oxymetazoline HCL 0.05%

Nasal Decongestant

1.0 FLOZ (30ml)



## Principal Display panel -Carton

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## FAMILY WELLNESS OXYMETAZOLINE SINUS SEVERE

oxymetazoline spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-827
<b>Route of Administration</b>	NASAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CITRIC ACID ACETATE</b> (UNII: DSO12WL7AU)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-827-30	1 in 1 CARTON	09/30/2023	
1		30 mL in 1 BOTTLE; 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	09/30/2023	

**Labeler** - FAMILY DOLLAR (Family Wellness) (024472631)

Revised: 8/2023

FAMILY DOLLAR (Family Wellness)