QUALITY CHOICE NASAL ORIGINAL- oxymetazoline hydrochloride spray QUALITY CHOICE (CHAIN DRUG MARKETING ASSOCIATION)

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.

Quality Choice Nasal Mist No Drip 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
- 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 at (1-800-222-1222).

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 Use: Shake well before use. Push down cap while turning counter-clockwise and remove cap. Remove clip under rim. Before using the first time, prime metered 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, even stroke and sniff deeply. Wipe nozzle clean after use. Replace clip under rim and secure cap after use.

Other information

- store at room temperature
- retain carton for future reference on full labeling

SAFETY SEALED: Do not use if printed seal over cap is broken or missing How to use:

Push down cap while turning counter-clockwise and remove cap. Remove clip under rim. Secure cap after use.

Inactive ingredients

benzalkonium chloride, benzyl alcohol, edetate disodium, microcrystalline cellulose and carboxymethylcellulose sodium, polyethylene glycol, povidone, purified water, sodium phosphate dibasic, sodium phosphate monobasic, xanthan gum.

Package/Label Principal Display Panel

QUALITY CHOICE®

NDC# **63868-077-01**

*Compare to Active Ingredient Afrin® No Drip Original

12 hour relief

Nasal Mist No Drip

Nasal Decongestant

Oxymetazoline HCI 0.05%

Nasal Solution

Fast and Powerful Congestion Relief

For Colds & Allergies

No Drip Pump Mist Won't Drip from Nose or Down Throat

Maximum Strength

Original

1 FL OZ (30mL)

IMPORTANT: Keep the carton for future labeling.

100% QC SATISFACTION GURANTEED

Distributed by C.D.M.A., Inc.©

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

Questions: 800-935-2362

*This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of $\mathsf{Afrin}^{\$}$ No Drip Original.



QUALITY CHOICE NASAL ORIGINAL

oxymetazoline hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-077
Route of Administration	NASAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZ OLINE HYDROCHLORIDE	.05 g in 100 mL	

	Inactive Ingredients	
ı	Ingredient Name	Strength

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics		
Color	WHITE (off white)	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63868- 077-01	1 in 1 CARTON	04/17/2019	
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	04/17/2019	

Labeler - QUALITY CHOICE (CHAIN DRUG MARKETING ASSOCIATION) (011920774)

Revised: 1/2022 QUALITY CHOICE (CHAIN DRUG MARKETING ASSOCIATION)