SOUND BODY NASAL- oxymetazoline hydrochloride spray Big Lots Stores, 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.

Big Lots, Inc Nasal Spray 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 (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: 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.

Other information

- store at 20-25°C (68-77°F)
- retain carton for future reference on full labeling

Inactive ingredients

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

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the Active Ingredient in $\operatorname{Afrin}^{\text{\ensuremath{\mathbb{R}}}}$ Original Nasal Spray

MAXIMUM STRENGTH ORIGINAL

Nasal Spray

Oxymetazoline HCl 0.05% - Nasal Decongestant

Fast, Powerful Congestion Relief For Colds & Allergies

12 HOUR RELIEF

#1 DOCTOR RECOMMENDED adult nasal spray active ingredient

1 FL OZ (30 mL)







MAXIMUM STRENGTH

Nasal

Oxymetazoline HCI 0.05% -

1 FLOZ(30 ML)

Nasal Decongestant

Congestion Relief

For Colds & Allergies

Fast, Powerful

ORIGINAL

Compare to the Active

Ingredient in Afrin®

Original Nasal Spray*



MAXIMUM STRENGTH

Oxymetazoline HCI 0.05% -

Nasal Decongestant

Congestion Relief

For Colds & Allergies

ed By: Perrigo Company 5 Eastern Avenue

Fast, Powerful

ORIGINAL

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Drug Facts (continued)

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*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Afrin® Original Nasal Spray.



GLUTEN FREE

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING



30410 TM C4

SOUND BODY NASAL

oxymetazoline hydrochloride spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source)

NDC:50594-017

Route of Administration

NASAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE -	OXYMETAZOLINE	0.05 g
UNII:8 VLN5B44ZY)	HYDROCHLORIDE	in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SO DIUM PHO SPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
SODIUM PHO SPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980 JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

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

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:50594-017- 10	1 in 1 CARTON	05/03/2016		
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	05/03/2016		

Labeler - Big Lots Stores, Inc. (017885351)

Revised: 11/2019 Big Lots Stores, Inc.