AVON HEXASHIELD CONGESTION RELIEF ORIGINAL- oxymetazoline hydrochloride spray

Tai Guk Pharm. Co., Ltd.

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.

AVON HeXashield Nasal Relief Spray Congestion Relief Original

Active Ingredient

Oxymetazoline HCl 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

For external use only.

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:** Shake well before use. To open, rotate cap to align the marks. Squeeze cap on both sides in a counterclockwise turn and pull off to remove. To spray, remove clamp and hold bottle with thumb at base and nozzle between first and second fingers. Without tilting the head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use and snap cap back onto the bottle.

Other information

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

Inactive Ingredients

benzalkonium chloride, edetate disodium, polyethylene glycol 400, povidone, propylene glycol, sodium phosphate dibasic, sodium phosphate monobasi dihydrate, water

Questions or comments?

Call toll free 1-800-FOR-AVON

www.avon.com

Principal Display Panel

HeXasheild

ORIGINAL

NASAL RELIEF SPRAY

CONGESTION RELIEF

Oxymetazoline HCl-

Nasal Decongestant

Compare to the active ingredient in Afrin [®] Original

Rapid & Powerful Congestion

Relief 12 Hour Relief

AVON

- Original Nas al Spray 12 HOURS
- Pump Mist
- Anti-Drip

NET WT 0.5 FL oz (15 mL)



AVON HEXASHIELD CONGESTION RELIEF ORIGINAL

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43136-105
Route of Administration	NASAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.05 g in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
PO VIDO NE (UNII: FZ989 GH94E)		
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)		
SODIUM PHO SPHATE, MO NO BASIC, DIHYDRATE (UNII: 5QWK665956)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:43136-105- 01	1 in 1 CARTON	07/31/2019	
1	15 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	07/31/2019	

Labeler - Tai Guk Pharm. Co., Ltd. (689060246)

Establishment				
Name	Address	ID/FEI	Business Operations	
Tai Guk Pharma. Co., Ltd.		689060246	manufacture(43136-105)	

Revised: 7/2019 Tai Guk Pharm. Co., Ltd.