

HALODINE NASAL ANTISEPTIC- povidone-iodine solution

Halodine LLC

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.

Halodine Nasal Antiseptic

Drug Facts

Active Ingredient

Povidone-Iodine USP, 1.25%

(0.125% Available Iodine)

Purpose

Antiseptic

Uses

- Antiseptic skin preparation
- Helps reduce bacteria that can potentially cause skin infection

Warnings

For external use only.

Do not use

- If allergic to iodine
- In the eyes
- On children less than 3 years old
- Over large areas of the body

Ask a doctor before use if injuries are

- Deep or puncture wounds
- Serious burns

Stop use and ask a doctor if irritation and redness develop or if condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

For nasal application

1. Gently blow nose to clear both nostrils. Discard tissue.
2. Open single ampoule by folding the narrow end along line. To avoid spill while opening, maintain ampoule with narrow end pointing up.
3. Place narrow end of ampoule at right nostril and gently pinch left nostril. Lift chin and tilt head back; squeeze all liquid from ampoule while inhaling through right nostril. Discard ampoule.
4. Open second ampoule by folding the narrow end along line. Avoid spill.
5. Place narrow end of ampoule at left nostril and gently pinch right nostril. Lift chin and tilt head back; squeeze all liquid from ampoule while inhaling through left nostril. Discard ampoule.

Note: Do not blow nose. If solution drips, wipe with tissue.

Other Information

- Single use only; do not reuse
- Not made with natural rubber latex
- Store at room temperature; avoid excessive heat

Inactive Ingredients

hydroxyethylcellulose, purified water

Questions or comments?

contact@halodine.com

HELPS REDUCE RISK OF INFECTION • 4-HOUR FORMULA

Non-sterile Solution

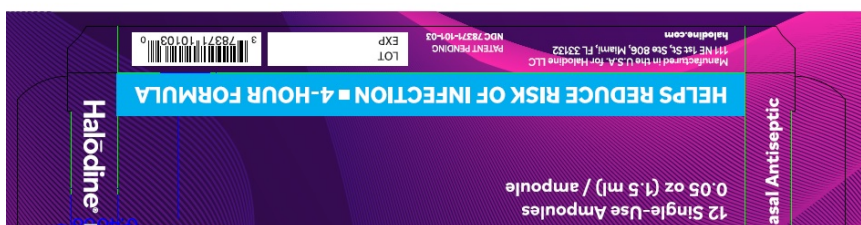
Manufactured in the U.S.A. for Halodine LLC

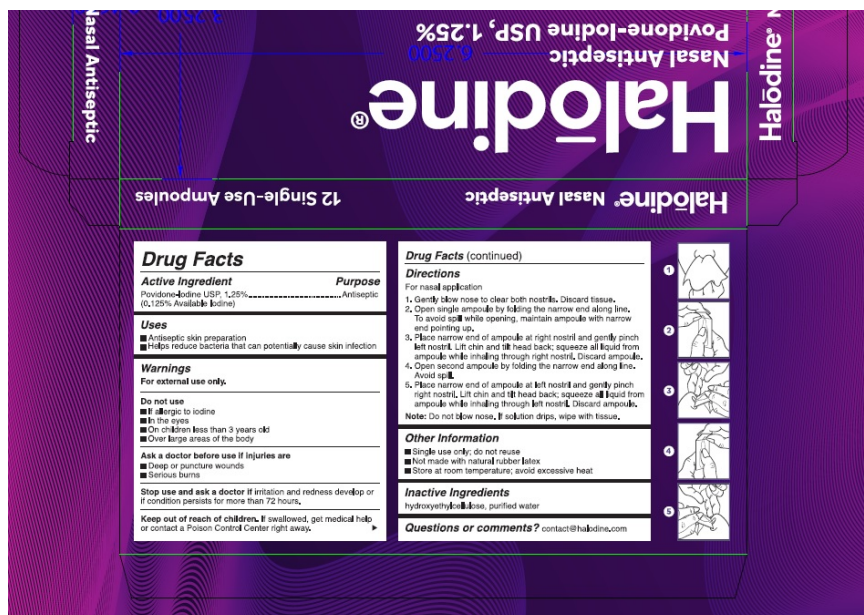
111 NE 1st St, Ste 806, Miami, FL 33132

halodine.com

Packaging

Package 12-single use Ampoules





Package 96-single use Ampoules



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Inactive Ingredients	
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HALODINE NASAL ANTISEPTIC

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78371-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78371-101-03	12 in 1 CARTON	10/28/2020	
1		1.5 mL in 1 AMPULE; Type 0: Not a Combination Product		
2	NDC:78371-101-01	96 in 1 CARTON	05/15/2020	
2		1.5 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/15/2020	

Labeler - Halodine LLC (117526113)

Revised: 6/2021

Halodine LLC