

HALODINE NASAL ANTISEPTIC SWABSTICK- 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 Swabstick

Drug Facts

Active Ingredient

Povidone-Iodine USP, 2.5%

(0.25% 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 swabstick. Hold tube between thumb and forefinger at blue band with handle up. With other hand, hold handle at base, and bend to snap open. Bend and snap in opposite direction to disconnect swabstick. Remove swabstick from tube.

- Apply medication. Insert swabstick comfortably into right nostril. Do not insert swab more than 1/4" past nasal opening. Rotate swab within nostril for a total of 15 seconds, using a gentle swirling motion. Discard tube and swabstick.
- Repeat steps 2 and 3 with second swabstick for left nostril.

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

Packaging



DRUG FACTS LABEL

<p>Drug Facts</p>	<p>Drug Facts (continued)</p> <p>Directions</p>
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Halodine

halodine.com
Patent Pending

2.1250

Halodine

Nasal Antiseptic Swabstick
Povidone-Iodine USP, 2.5%

6 Single-Use Swabsticks
0.5 ml / Swabstick

FRONT

Helps Reduce
Risk of Infection

4-Hour Formula

NDC: 78371-301-02



Halodine
Nasal Antiseptic Swabstick



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Povidone-iodine USP, 2.5% (0.25% Available Iodine)	Antiseptic
Uses ■ Antiseptic skin preparation	
Warnings For external use only. Do not use ■ If allergic to iodine ■ In the eyes ■ On children less than 3 years old 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.	
Directions Apply locally as needed.	
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	

1.4063

0.3750

0.7485

Manufactured in the U.S.A. for Halodine LLC 111 NE 1st St, Ste 806, Miami, FL 33132



HALODINE NASAL ANTISEPTIC SWABSTICK			
povidone-iodine solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78371-301
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)		IODINE	2.5 mg in 1 mL
Inactive Ingredients			

Ingredient Name			Strength	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78371-301-01	100 in 1 CARTON	07/24/2020	
1		0.5 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		
2	NDC:78371-301-02	6 in 1 BOX	10/06/2020	
2		0.5 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		
3	NDC:78371-301-12	20 in 1 CARTON	10/06/2020	
3		6 in 1 BOX		
3		0.5 mL in 1 TUBE, WITH APPLICATOR; 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	07/24/2020		

Labeler - Halodine LLC (117526113)

Revised: 10/2020

Halodine LLC