

POVIDINE IODINE - povidine iodine swab

Henry Schein 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.

Povidone Iodine Swabstick

Active Ingredient

Povidone Iodine 10% v/v

Purpose

Antiseptic

Uses :povidone iodine swabstick 3

- First aid antiseptic to help prevent skin infection in minor cuts, scrapes and burns.
- For preparation of the skin prior to surgery.
- Helps reduce bacteria that can potentially cause skin infections.

Warnings:

- **FOR EXTERNAL USE ONLY**

Do not use:

- As a first aid antiseptic for more than 1 week.
- In the eyes.
- Over large areas of the body.

Ask a doctor before use if you have:

- Deep puncture wounds
- Animal bites
- Serious burns

Stop Use:

- If irritation and redness develop
- If condition persists for more than 72 hours, consult a physician.

Keep Out Of Reach Of Children

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

Directions:

Tear at notch, remove applicator, use only once.

As a first aid antiseptic

- clean affected area
- apply 1 to 3 times daily
- may be covered with a sterile bandage, if bandaged let dry.

For preoperative patient skin preparation

- clean area
- apply to operative site prior to surgery using the applicator

Inactive Ingredient:povidone_iodine_swabstick

Inactive Ingredient: Nonoxynol-9, Water

For use as an

- first aid antiseptic
- pre-operative skin preparation

Principal Display Panel

povidone_iodine_swabstick

NDC#: 0404-5639-01

25 x 3 Swabsticks
Contains:

Antiseptic/Germicide
For External Use Only



POVIDONE-IODINE SWABSTICKS (3's)

112-5639

HENRY SCHEIN®

HENRY SCHEIN® 112-5639

POVIDONE-IODINE SWABSTICKS (3's)

Antiseptic/Germicide
For External Use Only

Drug Facts

Active Ingredient **Purpose**
Povidone iodine 10% Antiseptic

Uses

Antiseptic cleanser to help prevent skin infection in minor cuts, scrapes, and burns • For preparation of the skin prior to surgery
• Helps reduce bacteria that can potentially cause skin infection

Warnings

For External Use Only.

Do not use • In the eyes • As a first aid antiseptic for more than 1 week • Over large areas of the body

Ask a doctor before use if you have • Deep or puncture wounds • Animal bites • Serious wounds

Stop use and ask a doctor if • Condition worsens or persists for more than 72 hours • Irritation and redness develops

Keep out of reach of children • If swallowed, get medical help or contact a Poison Control Center immediately

Directions

Tear at notch • Remove applicator • Use only once

As a first aid antiseptic • Clean affected area • apply 1 to 3 times daily • May be covered with a sterile bandage
• If bandaged, let dry first

For preoperative patient skin preparation • Clean area • Apply to operative site prior to surgery using applicator

Other Information • Store at room temperature • Avoid excessive heat

Inactive Ingredients • Nonoxynol-9, water

Contains:

25 x 3 Swabsticks



Distributed By:
HENRY SCHEIN, INC.
Melville, NY 11747
Made in Israel

Rev 4/11

POVIDINE IODINE

povidone iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0404-5639
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	10 mL in 100 mL
---	------------------------	-----------------

Inactive Ingredients

Ingredient Name	Strength
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-5639-01	10 in 1 CASE		
1		25 in 1 BOX		
1		3 in 1 POUCH		
1		.9 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/17/2011	

Labeler - Henry Schein Inc (012430880)

Revised: 5/2011

Henry Schein Inc