

**FIRSTLINE MEDICAL THE I-STICK POVIDONE-IODINE ANTISEPTIC AMPULES -
povidone-iodine liquid**

The Wild Side, Llc dba Firstline Medical

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.

FIRSTLINE MEDICAL the i-stick Povidone-Iodine Antiseptic Ampules

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Active ingredient

Povidone-iodine 10%

Purpose

Antiseptic

Uses

- Patient preoperative skin preparation
- For preparation of the skin prior to surgery
- Helps to reduce bacteria that potentially can cause skin infection

Warnings

For external use only.

Do not use

- in the eyes

When using this product

keep out of eyes, ears, and mouth

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours
- infection occurs

Keep out of reach of children.

- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean the area
- reverse cardboard sleeve then crush at dot between thumb and forefinger
- allow solution to saturate tip
- apply product to the operative site prior to surgery using the applicator tip

Other information

- Store at room temperature away from light
- Keep from freezing or excessive heat

Inactive ingredients


- citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

Questions?

call 1-866-433-2131 Monday through Friday 9:00am-5:00pm est

LINE MEDICAL the i-stick Povidone-Iodine Antiseptic Ampules 25 count (41477-420-69)

- Representative Package Labeling

<p>Drug Facts</p> <p>Active ingredient: Povidone-Iodine 10% Purpose: First Aid Antiseptic</p> <p>Use: First Aid to help prevent infection in minor cuts, scrapes, and burns.</p> <p>Warnings: For external use only. Do not use in the eyes or inside your large areas of the body. Ask a doctor before use if you have a deep or puncture wound, a chemical burn, or a severe burn. Do not use with a product if the container is punctured or damaged. Do not use longer than 1 week unless directed by a doctor. Keep out of reach of children. If necessary, get medical help or contact Poison Control Center right away.</p> <p>Directions: • Clean the affected area. • Remove any dirt or debris from the area of the wound. • Allow solution to sublimate for 1-2 minutes. • Dry the area with a sterile bandage. • Change bandage as needed.</p> <p>Other information: • Do not use if the solution is cloudy or has a precipitate. • Keep out of reach of children.</p> <p>Contains: 25 ampules (0.17 fl. oz (5 mL) each)</p> <p>Questions? Call 1-866-433-2131 Monday through Friday 9:00am-5:00pm est.</p>	<p>POVIDONE-IODINE FIRST AID ANTISEPTIC</p>	<p>To order: www.thei-stick.com</p>	<p>NDC 41477-420-69</p> <p>POVIDONE-IODINE FIRST AID ANTISEPTIC</p>  <p>Manufactured for: The Wild Side, LLC 9401 State Highway 52 Wausau, WI, 54403 (866) 433-2131 For Ordering and Information: www.thei-stick.com</p> <p>25 – 0.17 fl. oz (5 mL) Ampules Net Contents 4.23 fl. oz (125 mL)</p>
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thei-stick.com POVIDONE-IODINE FIRST AID ANTISEPTIC

NDC 41477-420-69
 This Unit Not Labeled For Retail Sale
 This unit is packaged in an outer container. Please see outer container for drug facts information.
 Active ingredient: Povidone-iodine, 10%
 Applicator and contents sterile unless package is damaged.
 To report a serious adverse event contact 1-866-433-2131

0.17 FL. OZ (5 ML)



PEEL
▼
DOWN

Manufactured for: The Wild Side, LLC
9401 State Highway 52, Wausau, WI, 54403

FIRST LINE MEDICAL is a division of the Wild Side, LLC. The company was formed in 2003 by David D. Taylor, MD and Timothy J. Turbett, MD, after many discussions throughout medical school, residency, and private practice about ways to improve healthcare as well as improve physician efficiency.

"Our goal is to bring innovations to medicine that improve upon practices of today."

For more information on FIRSTLINE MEDICAL and the *i-stick*, please visit us on the Web at: www.thei-stick.com.

Product Features and Benefits



Actual Size

FIRSTLINE MEDICAL is proud to present the *i-stick*, a new concept in antiseptic cleansing.

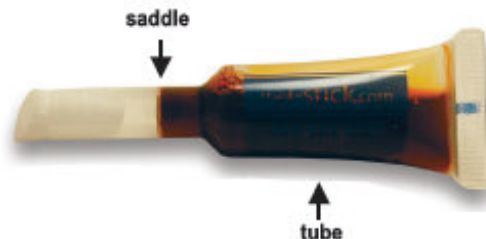
The *i-stick* allows you to:

- apply povidone-iodine through a controlled delivery system.
- eliminate the mess caused by traditional swabs and gauze.

How to use the *i-stick*

- 1) Squeeze gently at the saddle to break inner seal.
- 2) Apply light pressure to the middle of tube to dispense povidone-iodine onto the swab applicator tip.
- 3) Release pressure from ampoule when desired amount is applied.

The *i-stick*'s unique design allows the user to carefully control the flow of povidone-iodine.



thinking of ways to make healthcare better

FirstLine Medical

Manufactured for:
The Wild Side, LLC
9401 State Highway 52
Wausau, WI, 54403
Toll: 866-433-2131
Cell: 218-838-9484

FIRSTLINE MEDICAL THE I-STICK POVIDONE-IODINE ANTISEPTIC AMPULES

povidone-iodine liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41477-420

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41477-420-69	25 in 1 PACKAGE		
1		5 mL in 1 AMPULE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/15/2014	

Labeler - The Wild Side, Llc dba Firstline Medical (969962864)

Registrant - The Wild Side, Llc dba Firstline Medical (969962864)

Establishment

Name	Address	ID/FEI	Business Operations
James Alexander Corporation		040756421	manufacture(41477-420)

Establishment

Name	Address	ID/FEI	Business Operations
STERIS Isomedix		933290723	manufacture(41477-420)