

**PREVANTICS MAXI SWABSTICK- chlorhexidine gluconate and isopropyl alcohol solution**  
**Professional Disposables International, Inc.**

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**S27350- NDC 10819-4075-3**

**Active ingredients**

Chlorhexidine gluconate 3.15% w/v

Isopropyl alcohol 70% v/v

**Purposes**

Antiseptic

Antiseptic

**Use**

for the preparation of the patient's skin prior to surgery or injection

**Warnings**

- **For external use only**
- **Flammable, keep away from fire or flame**
- Do not use with electrocautery procedures

**Allergy alert**

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

if an allergic reaction occurs, stop use and seek medical help right away.

**Do not use**

- on patients allergic to chlorhexidine gluconate or any other ingredient in this product
- for lumbar puncture or in contact with the meninges
- on open skin wounds or as a general skin cleanser
- under occlusive patch

**When using this product**

keep out of eyes, ears, mouth and mucous membranes. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

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**Stop use and ask a doctor if**

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

## **Keep out of reach of children.**

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

## **Directions**

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- maximum treatment area for one swabstick is approximately: dry site: 7 by 7 inches (18 by 18 cm) or moist site: 3 by 7.5 inches (7.5 by 19 cm)
- tear open the pouch to expose the swabstick  
remove swabstick from package. Do not touch the foam tip.
- prior to surgery or injection, apply one flat side of foam tip to the proposed skin site and prep the skin in vigorous back-and-forth repeated strokes, turning the swabstick over (unused side of the foam tip) half way in the procedure
- **dry site:** scrub repeatedly back and forth for 15 seconds with each side of the applicator for a total of 30 seconds. Allow to air dry for approximately 30 seconds.
- **moist site:** scrub repeatedly back and forth for 1 minute with each side of the applicator for a total of 2 minutes. Allow to air dry for approximately 1.5 minutes.
- do not blot or wipe dry
- discard after a single use

## **Other information**

- store between 68-77°F (20-25°C)
- avoid freezing and excessive heat above 104°F (40°C)
- for hospital and professional use only

## **Inactive ingredients**

USP purified water

## **Questions?**

call **1-800-999-6423**, M-F (9:00 am-5:00 pm EST)

## **Package/Label Principal Display Panel**

**Reorder No. S27350**

**NDC 10819-4075-3**

**Pevantics (R) Maxi Swabstick**

**[Chlorhexidine Gluconate (3.15%)\* and Isopropyl Alcohol (70%) Swab]**

**Patient preoperative skin preparation**

**Non-Sterile solution**

**Packaging is sterile when in sterile kit**

\*equivalent to 161 mg of Chlorhexidine Gluconate per pouch

## **For external use only**




- Use for the preparation of the patient's skin prior to surgery or injection

- Helps reduce bacteria that potentially can cause skin infection
- For hospital and professional use only
- Latex free

**IMPORTANT:** See insert for complete *Drug Facts* and safety information.

One Maxi Swabstick, 0.172 fl. oz. (5.1 mL) Each

Packet Label

<p>NDC 10819-4075-3      REORDER NO. S27350</p> <p><b>Prevantics</b><sup>®</sup>          [Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]  <b>PATIENT PREOPERATIVE SKIN PREPARATION</b>  <b>Non-sterile Solution</b>  <b>Packaging is sterile when in sterile kit</b>  <small>*equivalent to 161 mg of Chlorhexidine Gluconate per pouch</small></p> <p><b>FOR EXTERNAL USE ONLY</b></p> <ul style="list-style-type: none"> <li>• Use for the preparation of the patient's skin prior to surgery or injection</li> <li>• Helps reduce bacteria that potentially can cause skin infection</li> <li>• For hospital and professional use only • Latex free</li> </ul> <p><b>IMPORTANT:</b> See insert for complete <i>Drug Facts</i> and safety information.</p> <p><b>One Maxi Swabstick, 0.172 fl.oz. (5.1 mL) Each</b></p>	 <p><b>MAXI SWABSTICK</b></p> 	<p><b>CONTENTS:</b> One Maxi Swabstick premoistened with 5.1 mL of a solution of 3.15% (w/v) Chlorhexidine gluconate, 70% (v/v) Isopropyl alcohol, and USP purified water.</p> <p><b>DIRECTIONS:</b> Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. Maximum treatment area for one maxi swabstick is approximately: dry site: 7 by 7 inches (18 by 18 cm) or moist site: 3 by 7.5 inches (7.5 by 19 cm). Tear open the pouch to expose the swabstick. Remove swabstick from package. Do not touch the foam tip. Prior to surgery or injection, apply one flat side of foam tip to the proposed skin site and prep the skin in vigorous back-and-forth repeated strokes, turning the swabstick over (lunated side of the foam tip) halfway in the procedure.</p> <p><b>Dry site:</b> Scrub repeatedly back and forth for 15 seconds with each side of the applicator for a total of 30 seconds. Allow to air dry for approximately 30 seconds. <b>Moist site:</b> Scrub repeatedly for 1 minute with each side of applicator for a total of 2 minutes. Allow to air dry for approximately 1.5 minutes. Do not blot or wipe dry. Discard after a single use.</p> <p><b>WARNINGS:</b> For external use only. <b>Flammable, keep away from fire or flame.</b> Do not use with electrocautery procedures.</p> <p><b>Allergy alert:</b> This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> <li>• wheezing/difficulty breathing • shock • facial swelling • hives • rash</li> </ul> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Professional Disposables International, Inc.          Orangeburg, NY 10962-1376 USA          1-800-999-6423 www.pdihc.com</p>  <p>(01)0031081900088</p>
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<p><b>REORDER NO. S27350</b>  <b>NDC 10819-4075-3</b></p>							
<p><b>Prevantics</b><sup>®</sup> <b>Maxi Swabstick</b>  <b>[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]</b>  <b>Patient preoperative skin preparation</b>  <b>Non-sterile Solution</b>  <b>Packaging is sterile when in sterile kit</b>  <small>*equivalent to 161mg of Chlorhexidine Gluconate per pouch</small></p>							
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### Drug Facts (continued)

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### Drug Facts (continued)

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Each Maxi Swabstick contains 0.172 fl. oz. (5.1 mL)



Professional Disposables International, Inc.  
Orangeburg, NY 10962-1376 USA  
1-800-999-6423 www.pdihc.com

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## PREVANTICS MAXI SWABSTICK

chlorhexidine gluconate and isopropyl alcohol solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10819-4075
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	31.5 mg in 1 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

### Inactive Ingredients

Ingredient Name

Strength

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10819-4075-3	300 in 1 CASE	01/15/2013	
1		5.1 mL in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021524	01/15/2013	06/01/2022

**Labeler** - Professional Disposables International, Inc. (800777117)

### Establishment

Name	Address	ID/FEI	Business Operations
Professional Disposables International, Inc.		800777117	manufacture(10819-4075)

Revised: 10/2019

Professional Disposables International, Inc.