

PREVANTICS SWABSTICK- chlorhexidine gluconate and isopropyl alcohol solution

Professional Disposables International, Inc.

S40750- NDC 10819-4077-1

S40750- NDC 10819-4077-4

S32450- NDC 10819-4077-2

S42850- NDC 10819-4077-3

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.

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 maxi swabstick is approximately: dry site: 4 by 4 inches (10 by 10 cm) or moist site: 3 by 5 inches (7.5 by 12.5 cm)
- tear open the pouch to expose the swabstick
- remove the 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

Package/Label Principal Display Panel

Packet Label

Non-sterile Solution Packaging is sterile when in sterile kit

*equivalent to 50 mg of Chlorhexidine Gluconate per pouch

Drug Facts	Drug Facts (continued)
<p>Active ingredients</p> <p>Chlorhexidine gluconate 3.15% w/v Antiseptic Isopropyl alcohol 70% v/v Antiseptic</p>	<p>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.</p>
<p>Use For the preparation of the patient's skin prior to surgery or injection</p>	<p>Do not use</p> <ul style="list-style-type: none"> • 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
<p>Warnings</p> <ul style="list-style-type: none"> • For external use only • Flammable, keep away from fire or flame • Do not use with electrocautery procedures 	

MISC027v00

<p>Drug Facts (continued)</p> <p>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.</p> <p>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Drug Facts (continued)</p> <p>back-and-forth repeated strokes, turning the swabstick over (unused side of the foam tip) halfway in the procedure</p> <ul style="list-style-type: none"> • 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 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>Directions</p> <ul style="list-style-type: none"> • 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: 4 by 4 inches (10 by 10 cm) or moist site: 3 by 5 inches (7.5 by 12.5 cm) • tear open the pouch to expose the swabstick • remove the 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 	<p>Other information</p> <ul style="list-style-type: none"> • store between 68-77°F (20-25°C) • avoid freezing and excessive heat above 104°F (40°C) • for hospital and professional use only <p>Inactive ingredient USP purified water</p> <p>Questions? call 1-800-999-6423, M-F (9:00 am-5:00 pm EST)</p>

Each swabstick contains 0.054 fl. oz. (1.6 mL)

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

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**REORDER NO. S42850
NDC 10819-4077-3**



Prevantics® 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 50 mg of Chlorhexidine Gluconate per pouch

Drug Facts

Active ingredients Purpose

Chlorhexidine gluconate 3.15% w/v. Antiseptic

Isopropyl alcohol 70% v/v. Antiseptic

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Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

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Inactive ingredient

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Questions?

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Professional Disposables International, Inc.
One





PREVANTICS SWABSTICK

chlorhexidine gluconate and isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10819-4077
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:10819-4077-4	50 in 1 BOX	06/01/2020	
1	NDC:10819-4077-1	1.6 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:10819-4077-2	500 in 1 CASE	06/01/2020	
2		1.6 mL in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:10819-4077-3	500 in 1 CASE	06/01/2020	
3		1.6 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	06/01/2020	

Establishment

Name	Address	ID/FEI	Business Operations
Professional Disposables International, Inc.		800777117	manufacture(10819-4077)

Revised: 3/2021

Professional Disposables International, Inc.