PREVANTICS MAXI SWABSTICK- chlorhexidine gluconate and isopropyl alcohol solution

Professional Disposables International, Inc.

S27350- NDC 10819-4076-3 S41950- NDC-10819-4076-4

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

To reduce the risk of fire, PREP CAREFULLY:

- solution contains alcohol and gives off flammable vapors
- avoid getting solution into hairy areas. Hair may take up to 1 hour to dry. Wet hair is flammable.
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)
- do not allow solution to pool
- remove wet materials from prep area

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 swabstick is approximately 8.4 in. x 8.4 in. (21.3 cm by 21.3 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) halfway 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 for 1 minute with each side of the applicator for a total of 2 minutes. Allow to air dry for approximately 1.5 minutes.
- if using an ignition source, allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).
- do not blot or wipe away
- 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

Prevantics(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

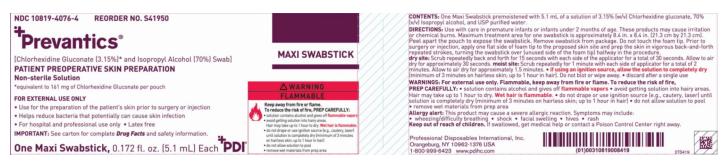
*equivalent to 161 mg of Chlorhexidine Gluconate per pouch

- 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

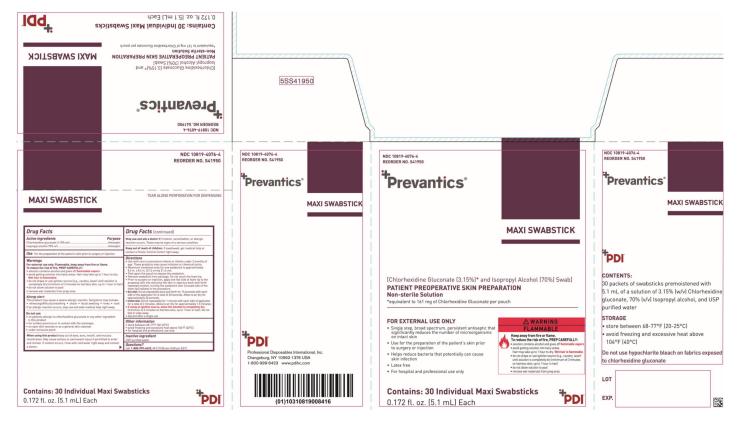
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IMPORTANT: See carton for complete **Drug Facts** and safety information.

Packet Label



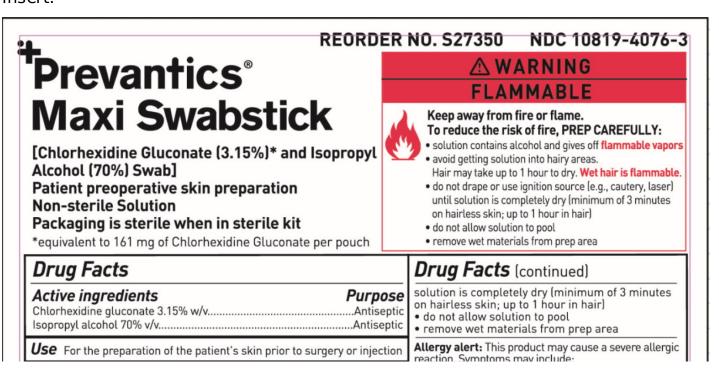
Box Label



Packet (bulk):



Insert:



Warnings

For external use only. Flammable, keep away from fire or flame. To reduce the risk of fire, PREP CAREFULLY:

- solution contains alcohol and gives off flammable vapors
- avoid getting solution into hairy areas. Hair may take up to 1 hour to dry. Wet hair is flammable.
- do not drape or use ignition source (e.g., cautery, laser) until

 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

Drug Facts (continued)

- 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

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 8.4 in. x 8.4 in. (21.3 cm by 21.3 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) halfway in the procedure.

Drug Facts (continued)

- 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.
- if using an ignition source, allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
- 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 ingredient

USP purified water

Questions?

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

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:10819-4076

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength

CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE -

CHI ORHEXIDINE

31.5 ma

UNII:R4KO0DY52L)	GLUCONATE	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- 4076-4	30 in 1 BOX	12/01/2023	
1		5.1 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:10819- 4076-3	300 in 1 CASE	09/01/2023	
2		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	01/01/2020	

Labeler - Professional Disposables International, Inc. (800777117)

Establishment				
Name	Address	ID/FEI	Business Operations	
Professional Disposables International, Inc.		800777117	manufacture(10819-4076)	

Revised: 6/2023 Professional Disposables International, Inc.