

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
-

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

Packet Label

<p>NDC 10819-4076-4 REORDER NO. S41950</p> <p>Prevantics®</p> <p>[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]</p> <p>PATIENT PREOPERATIVE SKIN PREPARATION</p> <p>Non-sterile Solution</p> <p>*equivalent to 161 mg of Chlorhexidine Gluconate per pouch</p> <p>FOR EXTERNAL USE ONLY</p> <ul style="list-style-type: none">• 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 <p>IMPORTANT: See carton for complete Drug Facts and safety information.</p> <p>One Maxi Swabstick, 0.172 fl. oz. (5.1 mL) Each</p> 	<p>MAXI SWABSTICK</p> <p>WARNING</p> <p>FLAMMABLE</p> <p>Keep away from fire or flame.</p> <p>To reduce the risk of fire, PREP CAREFULLY:</p> <ul style="list-style-type: none">• 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	<p>CONTENTS: 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>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). Peel apart 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.</p> <p>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</p> <p>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</p> <p>• remove wet materials from prep area</p> <p>Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none">• wheezing/difficulty breathing• shock• facial swelling• hives• rash <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Professional Disposables International, Inc. Orangetown, NY 10962-1378 USA 1-800-999-6423 www.pdihc.com</p>  <p>(01)00310819008419</p>  <p>2TS419</p>
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Box Label

Contains: 30 Individual Maxi Swabsticks
0.172 fl. oz. (5.1 mL) Each

Prevantics®
NDC 10819-4076-4
REORDER NO. 541950

MAXI SWABSTICK

TEAR ALONG PERFORATION FOR DISPENSING

Drug Facts	Purpose
Active ingredients Chlorhexidine gluconate 3.15% w/v..... Isopropyl alcohol 70% v/v.....	Antiseptic

Drug Facts (continued)

Directions
• Use on clean, dry, 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.
• Hold against the skin to be treated for 15 seconds with each side of application for a total of 30 seconds. Allow to air dry for approximately 1.5 minutes. If using an 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.

Warnings
• For external use only. Flammable, keep away from fire or flame.
• 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.

Precautions
• For hospital and professional use only.

Other information
• Contains 161 mg Chlorhexidine gluconate per pouch.
• Contains 30 individual Maxi Swabsticks per pouch.
• Contains 0.172 fl. oz. (5.1 mL) solution per pouch.
• Contains 161 mg Chlorhexidine gluconate per pouch.
• Contains 30 individual Maxi Swabsticks per pouch.
• Contains 0.172 fl. oz. (5.1 mL) solution per pouch.

Contains: 30 Individual Maxi Swabsticks
0.172 fl. oz. (5.1 mL) Each

SSS41950

Prevantics®
NDC 10819-4076-4
REORDER NO. 541950

MAXI SWABSTICK

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

(01)10310819008416

NDC 10819-4076-4
REORDER NO. 541950

Prevantics®

MAXI SWABSTICK

[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]
PATIENT PREOPERATIVE SKIN PREPARATION
Non-sterile Solution
*equivalent to 161 mg of Chlorhexidine Gluconate per pouch

FOR EXTERNAL USE ONLY

- Single step, broad spectrum, persistent antiseptic that significantly reduces the number of microorganisms on intact skin
- Use for the preparation of the patient's skin prior to surgery or injection
- Helps reduce bacteria that potentially can cause skin infection
- Latex free
- For hospital and professional use only

WARNING 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

Contains: 30 Individual Maxi Swabsticks
0.172 fl. oz. (5.1 mL) Each

NDC 10819-4076-4
REORDER NO. 541950

Prevantics®

MAXI SWABSTICK

PDI

CONTENTS:
30 packets of swabsticks premoistened with 5.1 mL of a solution of 3.15% (w/v) Chlorhexidine gluconate, 70% (v/v) Isopropyl alcohol, and USP purified water

STORAGE
• store between 68-77°F [20-25°C]
• avoid freezing and excessive heat above 104°F (40°C)

Do not use hypochlorite bleach on fabrics exposed to chlorhexidine gluconate

LOT
EXP.

Packet (bulk):

NDC 10819-4076-3 REORDER NO. 527350

Prevantics®
[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

WARNING 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

CONTENTS: 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.

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 (lunated 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 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.

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

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

(010031081900888)

Insert:

REORDER NO. S27350 NDC 10819-4076-3

Prevantics®
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

WARNING 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

Drug Facts	Purpose
Active ingredients Chlorhexidine gluconate 3.15% w/v..... Isopropyl alcohol 70% v/v.....	Antiseptic

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

Drug Facts (continued)
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:

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

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

MISC027v00

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 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.

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

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE -	CHLORHEXIDINE	31.5 mg

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.