

PREVANTICS SWAB- chlorhexidine gluconate and isopropyl alcohol solution
Professional Disposables International, Inc.

B11400- NDC 10819-1080-2

Active ingredients

Chlorhexidine gluconate 3.15% w/v

Isopropyl alcohol 70% v/v

Purpose

Antiseptic

Antiseptic

Use

for the preparation of the patient's skin prior to an 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 ingredients 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 swab is approximately 2.5 by 2.5 inches (6 by 6 cm)
- tear open packet and remove swab. Do not unfold swab.
- prior to injection, apply swab to the procedure site by holding swab between thumb and index finger. Apply swab to skin using repeated back-and-forth strokes for 15 seconds.
- allow the prepped area to air dry for 30 seconds
- 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

Reorder No. B11400

NDC 10819-1080-2

Prevantics(R) Swab

Chlorhexidine Gluconate (3.15%) and Isopropyl Alcohol (70%) swab

Antiseptic

Non-Sterile Solution

Packagind is sterile when in sterile kits

For external use only

Use for the preparation of the patient's skin prior to an 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.

Packet label



<p>NDC 10819-1080-2 REORDER NO. B11400</p> <p>Prevantics®</p> <p>[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]</p> <p>ANTISEPTIC</p> <p>Non-sterile Solution</p> <p>Packaging is sterile when in sterile kit</p> <p>*equivalent to 167 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 an injection• Helps reduce bacteria that potentially can cause skin infection• For hospital and professional use only • Latex free• Do not use with electrocautery procedures <p>IMPORTANT: See insert for complete Drug Facts and safety information.</p> <p>One Swab, 0.034 fl. oz. (1 mL) Each</p>  <p>(01)00310819000864</p>  <p>SWAB</p>	<p>CONTENTS: One swab premoistened with 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 swab is approximately 2.5 by 2.5 inches (6 by 6 cm). Tear open packet and remove swab. Do not unfold swab. Prior to injection, apply swab to the procedure site by holding swab between thumb and index finger. Apply swab to skin using repeated back-and-forth strokes for 15 seconds. Allow the prepped area to air dry for 30 seconds. Do not blot or wipe dry. Discard after a single use. WARNINGS: For external use only. Flammable, keep away from fire or flame.</p> <p>Allergy Alert This product may cause a severe allergic reaction. Symptoms 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.</p> <p>Professional Disposables International, Inc. Orangeburg, NY 10962-1376 USA 1-800-999-6423 www.pdihc.com</p> 
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LOT EXP.

Insert

<p>Prevantics® Swab REORDER NO. B11400 NDC 10819-1080-2</p> <p>[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab] Antiseptic Non-sterile Solution • Packaging is sterile when in sterile kit</p> <p>*equivalent to 32 mg of Chlorhexidine Gluconate per pouch</p> <p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Chlorhexidine gluconate 3.15% w/v</td><td>Antiseptic</td></tr><tr><td>Isopropyl alcohol 70% v/v</td><td>Antiseptic</td></tr></tbody></table> <p>Use For the preparation of the patient's skin prior to an injection</p> <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 <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>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>When using this product keep out of eyes, ears, mouth, and mucous membranes. May cause serious or permanent</p>	Active ingredients	Purpose	Chlorhexidine gluconate 3.15% w/v	Antiseptic	Isopropyl alcohol 70% v/v	Antiseptic	<p>Drug Facts (continued)</p> <p>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>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 swab is approximately 2.5 by 2.5 inches (6 by 6 cm)• tear open packet and remove swab. Do not unfold swab.• prior to injection, apply swab to the procedure site by holding swab between thumb and index finger. Apply swab to skin using repeated back-and-forth strokes for 15 seconds.• allow the prepped area to air dry for 30 seconds• do not blot or wipe dry• discard after a single use <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> <p>Each Swab contains 0.034 fl. oz. (1 mL)</p> <p>PDI Professional Disposables International, Inc. Orangeburg, NY 10962-1376 USA 1-800-999-6423 www.pdihc.com</p>   <p>5QB114IS</p>
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Chlorhexidine gluconate 3.15% w/v	Antiseptic						
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PREVANTICS SWAB

chlorhexidine gluconate and isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10819-1080
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:10819-1080-2	3000 in 1 CASE	01/15/2013	
1		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	

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

Name	Address	ID/FEI	Business Operations
Professional Disposables International, Inc.		800777117	manufacture(10819-1080)

Revised: 10/2022

Professional Disposables International, Inc.