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

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#### B10800 NDC 10819-1080-1

#### **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 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 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

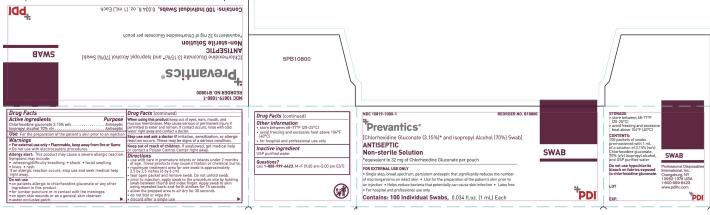
USP purified water

## Package/Label Principal Display Panel

Packet Label

#### TEAR BELOW NDC 10819-1080-1 REORDER NO. B10800 CONTENTS: One swab premoistened with 1 mL of a solution of 3.15% (w/v) <sup>+</sup>Prevantics<sup>®</sup> Chlorhexidine gluconate, 70% (v/v) Isopropyl alcohol, and USP purified water. DIRECTIONS: Use with care in premature infants or infants under 2 Chlorhexidine Gluconate (3.15%)\* months of age. These products may cause irritation or chemical burris. 9 and Isopropyl Alcohol (70%) Swab] Maximum treatment area for one swab is approximately 2.5 by 2.5 inches SWAB ANTISEPTIĆ (6 by 6 cm). Tear open packet and remove swab. Do not unfold swab. Prior Non-sterile Solution to injection, apply swab to the procedure site by holding swab between tequivalent to 32 mg of Chlorhexidine Gluconate per pouch FOR EXTERNAL USE ONLY thumb and index finger. Apply swab to skin using repeated back-and-forth EXP. strokes for 15 seconds. Allow the prepped area to air dry for 30 seconds. Use for the preparation of the patient's skin prior to an injection Do not blot or wipe dry. Discard after a single use. Helps reduce bacteria that potentially can cause skin infection WARNINGS: For external use only. Flammable, keep away from fire or flame. For hospital and professional use only • Latex free Allergy alert: This product may cause a severe allergic reaction. Do not use with electrocautery procedures Symptoms may include: **IMPORTANT:** See carton for complete Symptoms may include: • wheezing/difficulty breathing • shock • facial swelling • hives • rash Keep out of reach of children. If swallowed, get medical help or **Drug Facts** and safety information. **One Swab,** 0.034 fl. oz. (1 mL) Each contact a Poison Control Center right away. Professional Disposables International, Inc., Orangeburg, NY 10962-1376 USA (01)00310819000017 1-800-999-6423 www.pdihc.com 2TB108

# Box Label



Route of Administration TOPICAL   Active Ingredient/Active Moiety   Ingredient Name Basis of Strength   CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4K00DY52L) CHLORHEXIDINE - GLUCONATE   ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - ISOPROPYL ALCOHOL -	FICS SWAB gluconate and isopro	pyl alcohol solut	ion					
Product Type HUMAN OTC DRUG Item Code (Source) NDC:1081   Route of Administration TOPICAL MDC:1081   Active Ingredient/Active Moiety Basis of Strength CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4K00DY52L) Basis of Strength 3   ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - ISOPROPYL ALCOHOL -								
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				ISOPROPYL ALCOHOL 0.7 mL in 1 mL				
Inactive Ingredients	gredients							
Ingredient Name Strengt	Ingredient Name					Strength		
WATER (UNII: 059QF0K00R)	059QF0KO0R)							

Packaging							
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:10819- 1080-1	100 in 1 BOX	01/15/2013				
1	1 mL in 1 POUCH; Type 0: Not a Combination Product						
Μ	arketing	Information					
M	arketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			

Labeler - Professional Disposables International, Inc. (800777117)

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

Revised: 10/2023

Professional Disposables International, Inc.