

CHLORAPREP SWABSTICK- chlorhexidine gluconate and isopropyl alcohol solution
CareFusion 213 LLC

ChloraPrep™ Swabsticks

Active ingredients

Chlorhexidine gluconate (CHG), 2% w/v
and Isopropyl alcohol (IPA), 70% v/v

Purpose

Antiseptic

Use

for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

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

When using this product,

keep out of eyes, ears, and mouth. 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.
- maximal treatment area using
- one single swabstick applicator is approximately 2.5 in. x 2.5 in. (42 cm²)
- three swabsticks sequentially is approximately 5 in. x 5 in. (160 cm²)
- tear pouch at side notch to reveal applicator handles. Do not touch foam applicator tip. Place foam flat side down on the treatment area.
- completely wet the treatment area with antiseptic
- **dry surgical sites** (e.g., abdomen or arm): use repeated back-and-forth strokes for 30 seconds. (When using the triple swabstick applicators, use each swabstick sequentially within the 30 seconds). Allow the area to air dry for approximately 30 seconds. Do not blot or wipe away.
- **moist surgical sites** (e.g., inguinal fold): use repeated back-and-forth strokes for 2 minutes. (When using the triple swabstick applicators, use each swabstick sequentially within the 2 minutes). Allow the area to air dry for approximately 1 minute. Do not blot or wipe away.
- discard the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.

Other information

- store between 15-30 °C (59-86 °F)
- avoid freezing and excessive heat above 40 °C (104 °F)

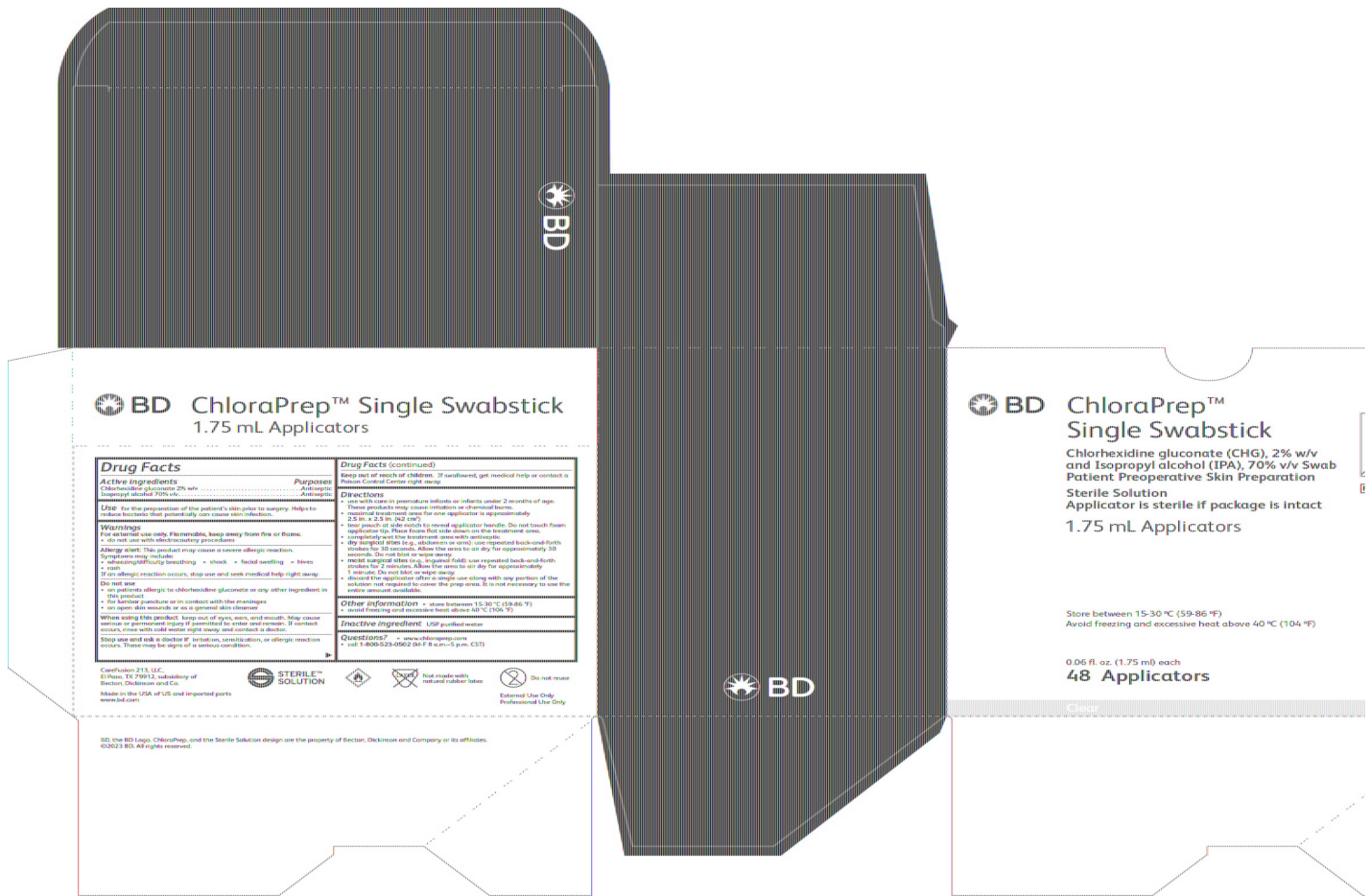
Inactive ingredient

- USP purified water

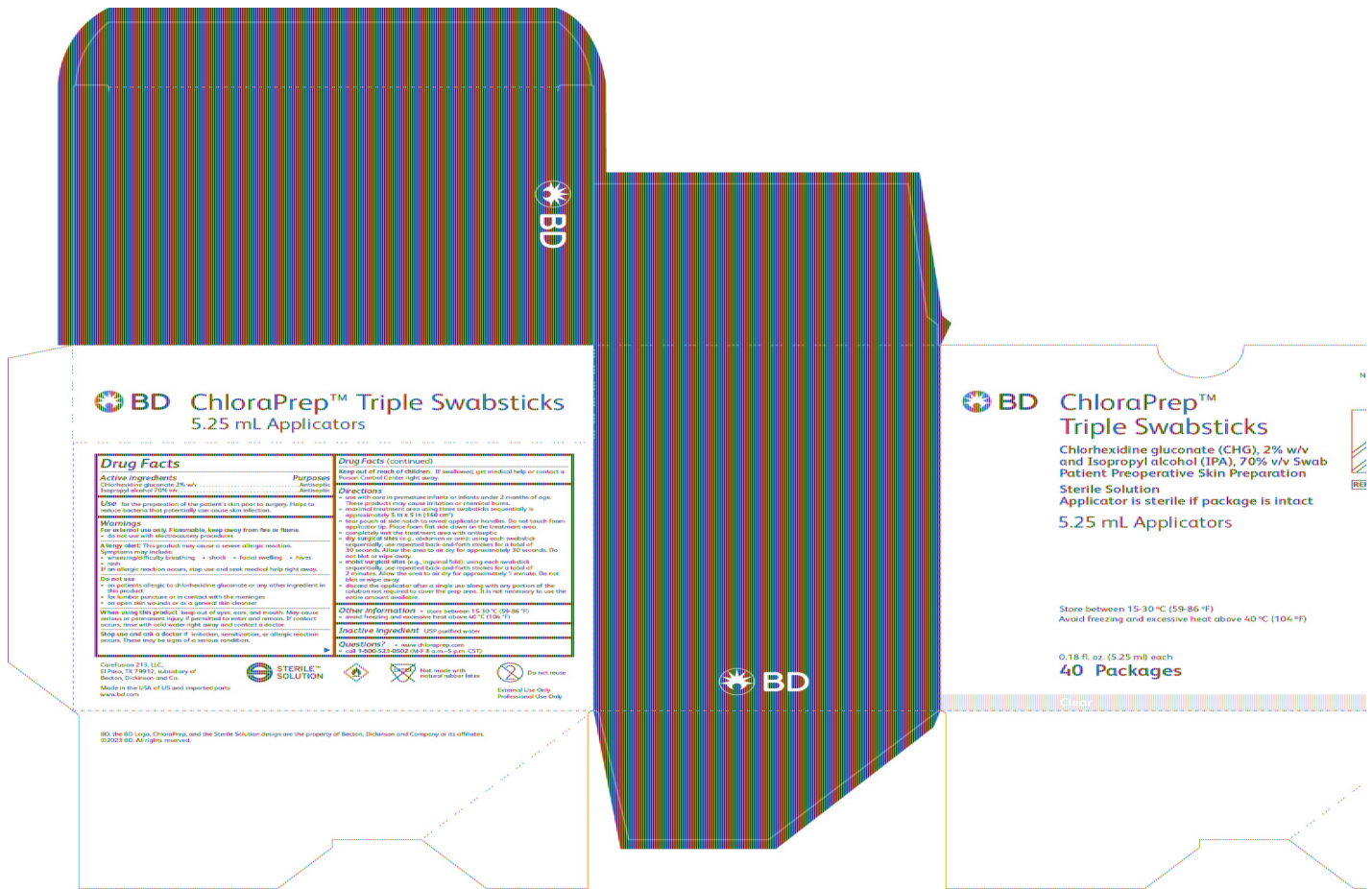
Questions?

- www.chloraprep.com
- call **1-800-523-0502** (M-F 8 a.m.-5 p.m. CST)

Package/Label Principal Display Panel



PRINCIPAL DISPLAY PANEL-CARTON
 BD ChloraPrep™ Single Swabstick
 Chlorhexidine gluconate (CHG), 2% w/v
 and Isopropyl alcohol (IPA), 70% v/v Swab
 Patient Preoperative Skin Preparation
 Sterile Solution
 Applicator is sterile if package is intact
 1.75 mL Applicators
 NDC 054365-401-28
 Ref 930100



PRINCIPAL DISPLAY PANEL-CARTON
 BD Chloraprep™ Triple Swabstick
 Chlorhexidine gluconate (CHG), 2% w/v
 and Isopropyl alcohol (IPA), 70% v/v Swab
 Patient Preoperative Skin Preparation
 Sterile Solution
 Applicator is sterile if package is intact
 5.25 mL Applicators
 NDC 054365-401-29
 Ref 930103

CHLORAPREP SWABSTICK

chlorhexidine gluconate and isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54365-401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 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:54365-401-28	48 in 1 CARTON	05/13/2024	
1		1 in 1 POUCH		
1		1.75 mL in 1 APPLICATOR; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NDC:54365-401-29	40 in 1 CARTON	05/13/2024	
2		3 in 1 POUCH		
2		5.25 mL in 1 APPLICATOR; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021555	05/13/2024	

Labeler - CareFusion 213 LLC (826496312)

Registrant - Becton, Dickinson and Company (832696038)

Establishment			
Name	Address	ID/FEI	Business Operations
CareFusion 213 LLC		826496312	manufacture(54365-401) , analysis(54365-401) , label(54365-401) , pack(54365-401) , sterilize(54365-401)