CHLORAPREP ONE-STEP- chlorhexidine gluconate and isopropyl alcohol solution
CareFusion 213 LLC

ChloraPrep® Swabsticks

Active ingredients

Chlorhexidine gluconate 2% w/v

Isopropyl alcohol 70% v/v

Purposes

Antiseptic

Antiseptic

Use

for the preparation of the patient's skin prior to surgery or injection. 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 for one applicator is approximately 2.5 in. x 2.5 in. (42 cm^2)
- 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 gentle repeated back-and-forth strokes for 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 gentle repeated back-and-forth strokes for 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 ºC (59-86 °F)
- avoid freezing and excessive heat above 40 ºC (104 °F)

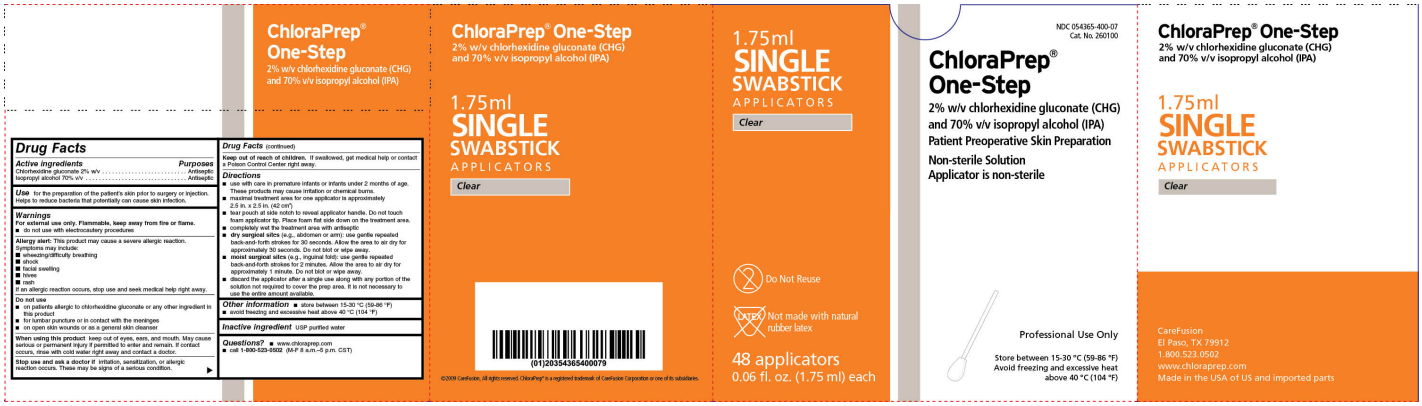
Inactive ingredient

- 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

1.75ml

SINGLE SWABSTICK

APPLICATORS

Clear

Do Not Reuse

Not made with natural rubber latex

48 applicators

0.06 fl. oz. (1.75 ml) each

NDC 054365-400-07

Cat. No. 2601000

ChloraPrep ® One-Step

2% w/v chlorhexidine gluconate (CHG)

and 70% v/v isopropyl alcohol (IPA)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is non-sterile

Professional Use Only

Store between 15-30 ºC (59-86 ºF)

Avoid freezing and excessive heat

above 40 ºC (104 ºF)

CHLORAPREP ONE-STEP

chlorhexidine gluconate and isopropyl alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54365-400

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:54365-400-07	48 in 1 CARTON	05/10/2005	
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:54365-400-03	200 in 1 CARTON	10/07/2002	03/31/2019
2		1 in 1 POUCH		
2		0.67 mL in 1 APPLICATOR; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
3	NDC:54365-400-08	40 in 1 CARTON	06/10/2009	
3		3 in 1 POUCH		
3		1.75 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	10/07/2002	

Labeler - CareFusion 213 LLC (826496312)

Registrant - Becton, Dickinson and Company (832696038)

Establishment

Name	Address	ID/FEI	Business Operations
CareFusion 213 LLC		826496312	manufacture(54365-400) , analysis(54365-400) , label(54365-400) , pack(54365-400) , sterilize(54365-400)