

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

Chloraprep® 5.25ml Triple Swabstick Applicator

Active ingredients

Chlorhexidine gluconate 2% w/v

Isopropyl alcohol 70% v/v

Purposes

Antiseptic

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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

Do not use

- on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol
- 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 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 gentle repeated back-and-forth strokes for 30 seconds (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 gentle repeated back-and-forth strokes for 2 minutes (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 ingredients

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

NDC 054365-400-08

5.25ml
TRIPLE
SWABSTICK
APPLICATORS

Clear



Do Not Reuse



Not made with natural
rubber latex

40 packages
0.18 fl. oz. (5.25 ml) each

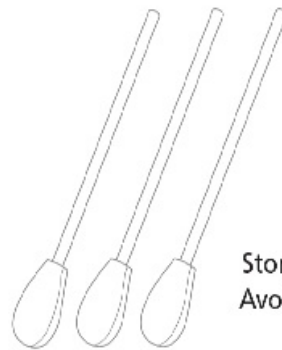
ChloroPrep[®]

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

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Avoid freezing and excessive heat
above 40 °C (104 °F)

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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	.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:54365-400-08	40 in 1 CARTON		
1		3 in 1 POUCH		
1		1.75 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021555	05/10/2005	

Labeler - CareFusion 213 LLC (826496312)

Registrant - CareFusion 213 LLC (831684456)

Establishment

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

Revised: 4/2015

CareFusion 213 LLC