CHLORAPREP ONE-STEP- chlorhexidine gluconate and is opropyl 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

Antiseptic

Use

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

Warnings

For external use only. Flammable, keep away from fire or flame. To reduce risk of fire, PREP CAREFULLY:

- solution contains alcohol and gives off flammable vapors
- avoid getting solution into hairy areas. Hair may take up to 1 hour to dry. **Wet hair is flammable.**
- do not use with ignition source (e.g. cautery, laser)
- do not allow solution to pool
- remove all wet materials from prep area

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.
- use in a well ventilated area
- 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
- **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes
- **allow the solution to completely dry** (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
- discard the applicators 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)

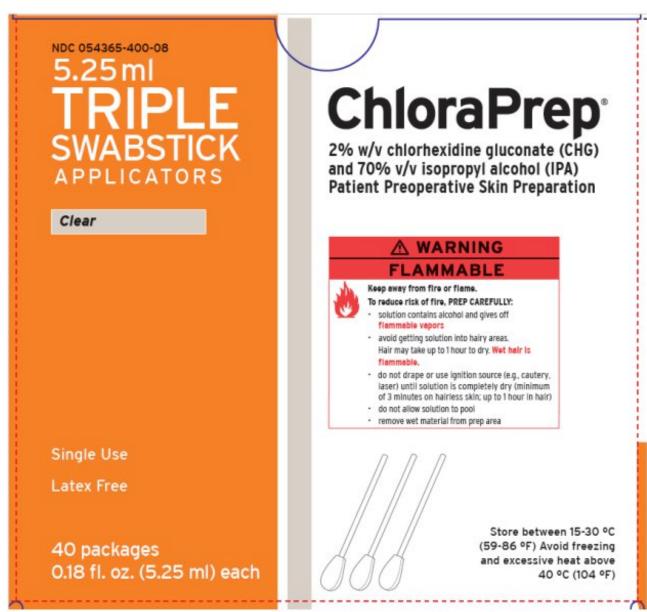
Inactive ingredients

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



Triple Swabstick Carton Primary Display Panel

NDC 054365-400-08

5.25ml TRIPLE SWABSTICK APPLICATORS

Clear

Single Use

Latex Free

40 packages

0.18 fl. oz. (5.25 ml) each

ChloraPrep®

2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA)

Patient Preoperative Skin Preparation

WARNING FLAMMABLE

Keep away from fire or flame.

To reduce risk of fire, PREP CAREFULLY:

- solution contains alcohol and gives off flammable vapors
- avoid getting solution into hairy areas. Hair may take up to 1 hour to dry. Wet hair is flammable.
- do not use with ignition source (e.g. cautery, laser)
- do not allow solution to pool
- remove wet material from prep area

Store between 15-30 °C (59-86 °F)

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

CHLORAPREP ONE-STEP

chlorhexidine gluconate and isopropyl alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:54365-400
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHLORHEXIDINE GLUCONATE (CHLORHEXIDINE)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL	
ISOPROPYL ALCOHOL (ISOPROPYL ALCOHOL)	ISOPROPYL ALCOHOL	0.70 mL in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER	

P	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		

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		Business Operations
CareFusion 213 LLC		826496312	ANALYSIS(54365-400), MANUFACTURE(54365-400), LABEL(54365-400), PACK(54365-400)

Revised: 12/2012 CareFusion 213 LLC