

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

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**Chloraprep® Hi-Lite Orange® 10.5ml 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 the 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 drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)
- do not allow solution to pool
- remove 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 for one applicator is approximately 8.4 in. x 8.4 in. (457 cm<sup>2</sup>)
- remove applicator from package; do not touch sponge
- hold the applicator with the sponge down. Pinch wings only once to activate the ampule and release the antiseptic.
- wet the sponge by pressing and releasing the sponge against the treatment area until liquid is visible on the skin
- 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
- do not allow solution to pool; tuck prep towels to absorb solution, and then remove
- **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. do not allow solution to pool
- 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)
- the tint will slowly fade from the skin. Soap and water, or alcohol may be used to remove the tint if desired.

## Inactive ingredients

- FD&C yellow #6 dye
- USP purified water

## Questions?

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

## Package/Label Principal Display Panel

NDC 054365-400-12

# 10.5ml

## APPLICATORS

**Hi-Lite Orange®**



Not made with natural rubber latex

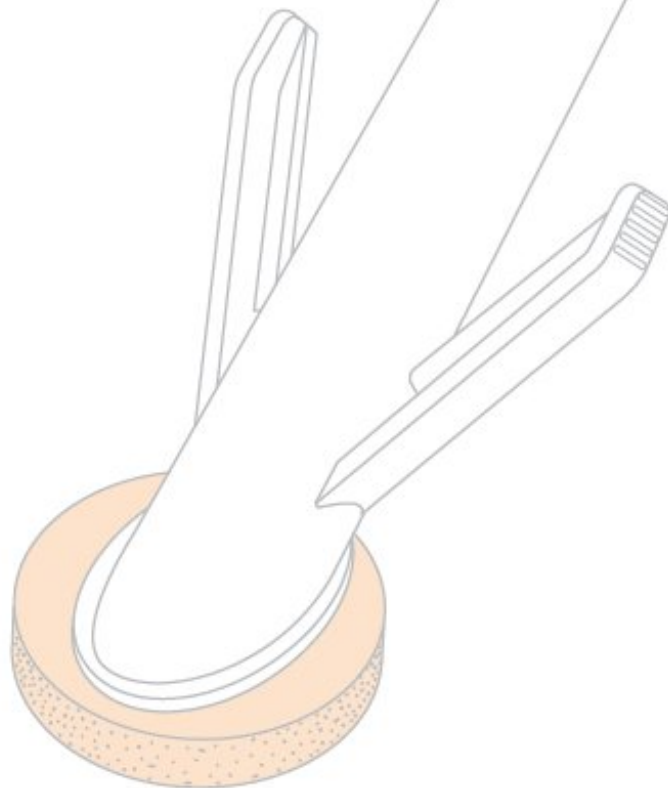
**STERILE EO**

Applicator is sterile if package is intact

Professional Use Only

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

**25 applicators**  
0.36 fl. oz. (10.5 ml) each



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### 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	0.7 mL in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER	
FD&C YELLOW NO. 6	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-12	25 in 1 CARTON		
1		1 in 1 POUCH		
1		10.5 mL in 1 APPLICATOR		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020832	08/18/2006	

**Labeler** - CareFusion 213 LLC (826496312)**Registrant** - CareFusion 2200, Inc (832696038)**Establishment**

Name	Address	ID/FEI	Business Operations
CareFusion 213 LLC		826496312	ANALYSIS(54365-400), MANUFACTURE(54365-400), LABEL(54365-400), PACK(54365-400)

Revised: 11/2013

CareFusion 213 LLC