

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

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**ChloroPrep® Hi-Lite Orange® 26ml Applicator**

**WARNING FLAMMABLE**

**Keep away from fire or flame.**

**To reduce risk of fire, PREP CAREFULLY:**

- do not use 26-ml applicator for head and neck surgery or on an area smaller than 8.4 in. × 8.4 in. Use a smaller applicator instead.
- 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

***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 bacteria that potentially can cause skin infection.

***Warnings***

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**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 13.2 in. x 13.2 in. (1126 cm<sup>2</sup>).
- remove applicator from package; do not touch sponge
- hold applicator with the sponge down. Pinch wing only once to activate the ampules 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.
- 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**



(01) 10354365400133

Cat. No. 260815 NDC 054365-400-13  
Single Use

### ChloroPrep® With Tint

2% w/v chlorhexidine gluconate (CHG)  
and 70% v/v isopropyl alcohol (IPA)  
Patient Preoperative Skin Preparation  
Non-sterile Solution  
Applicator is sterile if package is intact  
26 ml APPLICATOR

Hi-Lite Orange®

WARNING, FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

#### Drug Facts

| Active ingredients             | Purposes   |
|--------------------------------|------------|
| Chlorhexidine gluconate 2% w/v | Antiseptic |
| Isopropyl alcohol 70% v/v      | 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. To reduce risk of fire, PREP CAREFULLY:**
- do not use 26-ml applicator for head and neck surgery
  - do not use on an area smaller than 8.4 in. x 8.4 in. Use a smaller applicator instead.
  - solution contains alcohol and gives off flammable vapors
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- for lumbar puncture or in contact with the meninges
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#### Questions?

- www.chloroprep.com
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CareFusion, El Paso, TX 79912 • Artwork No. 6-786815 • M060514  
Made in the USA of US and imported parts

Single Use

## **ChloroPrep<sup>®</sup> With Tint**

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

Patient Preoperative Skin Preparation

### **Non-sterile Solution**

**Applicator is sterile if package is intact**

**26 ml APPLICATOR**

*Hi-Lite Orange<sup>®</sup>*

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### **DRUG FACTS**

#### **Active Ingredients and Purposes**

Chlorhexidine gluconate 2% w/v.....Antiseptic

Isopropyl alcohol 70% v/v.....Antiseptic

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CareFusion, El Paso, TX 79912

Made in the USA of US and imported parts

| <b>CHLORAPREP ONE-STEP</b>   |                |                           |                 |
|--|----------------|---------------------------|-----------------|
| chlorhexidine gluconate and isopropyl alcohol solution                       |                |                           |                 |
| <b>Product Information</b>   |                |                           |                 |
| <b>Product Type</b>  | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:54365-400   |
| <b>Route of Administration</b>   | TOPICAL        |                           |                 |
| <b>Active Ingredient/Active Moiety</b>                                       |                |                           |                 |
| <b>Ingredient Name</b>   |                | <b>Basis of Strength</b>  | <b>Strength</b> |
| 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  |
| <b>Inactive Ingredients</b>  |                |                           |                 |
| <b>Ingredient Name</b>   |                |                           | <b>Strength</b> |
| WATER (UNII: 059QF0KO0R)   |                |                           |                 |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)   |                |                           |                 |

## Packaging

| # | Item Code        | Package Description                                      | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:54365-400-13 | 1 in 1 POUCH   |                      |                    |
| 1 |                  | 26 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                | 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: 4/2015

CareFusion 213 LLC