

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

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**ChloraPrep® Hi-Lite Orange® 10.5ml Applicator**

**WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME**

**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 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***

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

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## **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 with known allergies 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.
- 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.

- 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)

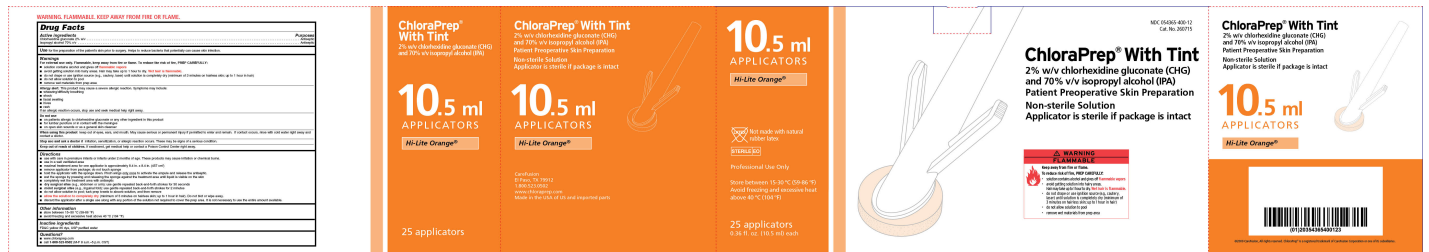
### Inactive ingredients

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



### PRINCIPAL DISPLAY PANEL-CARTON

**10.5 ml**

APPLICATORS

**Hi-Lite Orange**®

Not made with natural rubber latex

STERILE EO

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

NDC 054365-400-12

Cat. No. 260715

## Chloraprep<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

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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	0.7 mL in 1 mL

#### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

#### Packaging

Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-12	25 in 1 CARTON	08/18/2006	
1		1 in 1 POUCH		
1		10.5 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: 6/2021

CareFusion 213 LLC