

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

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**BD Chloraprep™ Hi-Lite Orange™ 26 mL Applicator with Sterile Solution**

**WARNING**  
**FLAMMABLE**

**Keep away from fire or flame.**

**To reduce the 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. x 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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**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 allergic 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

**13.2 in. x 13.2 in. (1126 cm<sup>2</sup>).** Do not use 26-mL applicator for area smaller than **8.4 in. x 8.4 in.** Use a smaller applicator instead. • do not use 26-mL applicator for head and neck surgery • remove applicator from package; do not touch sponge • hold the 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)

**BD ChloraPrep™ Hi-Lite Orange™ 26 mL Applicator Package Label**



# BD ChloroPrep™ Hi-Lite Orange™

## 26 mL Applicator

2% w/v chlorhexidine gluconate (CHG)  
and 70% v/v isopropyl alcohol (IPA)  
Patient Preoperative Skin Preparation

Sterile Solution

Applicator is sterile if package is intact

Hi-Lite Orange™

### ⚠ WARNING FLAMMABLE



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#### Drug Facts

##### Active Ingredients

Chlorhexidine gluconate 2% w/v.....	Antiseptic
Isopropyl alcohol 70% v/v.....	Antiseptic

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When using this product keep out of eyes, ears, and mouth. May cause irritation.

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.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### Directions

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Artwork No. 6-930841 • A050619 • Made in the USA of US and imported parts • [www.bd.com](http://www.bd.com)



(01)00354365400389

External Use Only  
Professional Use Only



STERILE EO



Package Label

BD Chloraprep™ Hi-Lite Orange™

26 mL Applicator

2% w/v chlorhexidine gluconate (CHG)

and 70% v/v Isopropyl alcohol (IPA)

Patient Preoperative Skin Preparation

Sterile Solution

Applicator is sterile if package is intact

REF 930815

NDC 54365-400-38

## CHLORAPREP ONE-STEP

chlorhexidine gluconate and isopropyl alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54365-400
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-38	1 in 1 POUCH	05/24/2019	
1		26 mL in 1 APPLICATOR; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020832	05/24/2019	

**Labeler** - CareFusion 213, LLC (826496312)

**Registrant** - Becton, Dickinson and Company (832696038)

### Establishment

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

