

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

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**ChloraPrep One-Step 1mL Non-sterile 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 bacteria that potentially can cause skin infection.

***Warnings***

**For external use only. Flammable, keep away from fire or flame.**

- do not use with electrocautery procedures

**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 in infants under 2 months of age. These products may cause irritation or chemical burns.
- maximal treatment area for one applicator is approximately 2.5 in. × 2.5 in. (42 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 approximately 30 seconds. Allow the area to air dry for approximately 30 seconds.
- **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes for approximately 2 minutes. Allow the area to air dry for approximately 1 minute.
- 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).

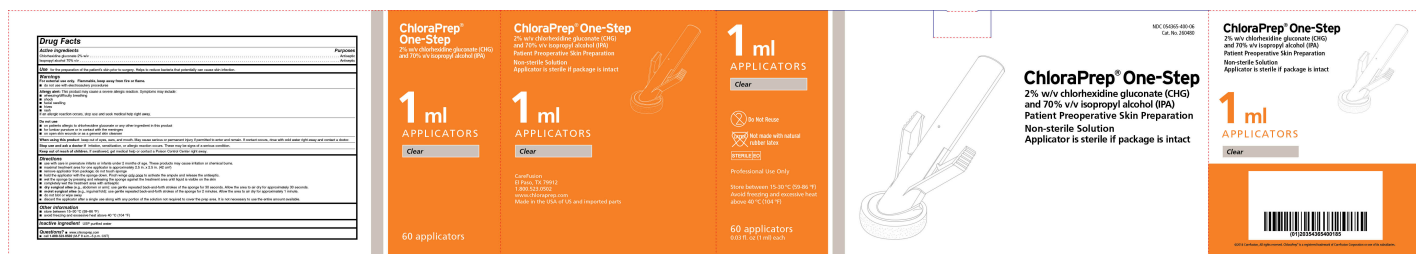
### **Inactive ingredients**

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 Principle Display Panel**



## PRINCIPAL DISPLAY PANEL-CARTON

**1 mL**

**APPLICATORS**

**Clear**

Do Not Reuse

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)

**60 applicators**

0.03 fl. oz. (1 mL) each

NDC 054365-400-06

Cat. No. 260480

**Chloraprep® One-Step**

**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**

## 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)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-06	60 in 1 CARTON	07/23/2014	
1		1 in 1 POUCH		
1		1 mL in 1 APPLICATOR; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020832	07/23/2014	

**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)

Revised: 11/2023

CareFusion 213 LLC