

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

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**ChlorPrep® Scrub Teal® 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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- 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 13.2 in. × 13.2 in. (1126 cm<sup>2</sup>).
- 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 back-and-forth strokes for 30 seconds
- **moist surgical sites** (e.g., inguinal fold): use gentle 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 green #3 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) 10354365400058

Cat. No. 260825 NDC 054365-400-05  
Single Use

### ChloroPrep® With Tint

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

Scrub Teal®

WARNING: FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

#### Drug Facts

Active ingredients	Purposes
Chlorhexidine gluconate 2% w/v	Antiseptic
Isopropyl alcohol 70% w/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

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- 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 lumbal 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

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#### Inactive ingredients

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#### Questions?

- www.chloroprep.com
- call 1-800-923-0002 (M-F 8 a.m.–5 p.m. CST)

Carefusion, El Paso, TX 79912 • Artwork No. 6-786825 • N000514  
Made in the USA of US and imported parts

NDC 054365-400-05

Single Use

## **ChloroPrep® With Tint**

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

Patient Preoperative Skin Preparation

### **Non-sterile solution**

**Applicator is sterile if package is intact**

### **26ml APPLICATOR**

Scrub Teal®

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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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#### **Inactive ingredients**

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USP purified water

#### **Questions?**

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- call **1-800-523-0502** (M-F 8 a.m.-5 p.m. CST)

CareFusion, El Paso, TX 79912

Made in USA of US and imported parts

## **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**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)				
WATER (UNII: 059QF0KO0R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-05	1 in 1 POUCH		
1		26 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA020832	04/26/2002		

**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)