

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

-----  
**ChloraPrep Clear 26 mL Applicator**

**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**

**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**
- 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

**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)

### ***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**

REF 930800  
NDC 54365-400-37

# BD ChloroPrep™ Clear

## 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

Clear

### **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. 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

#### **Drug Facts**

##### **Active Ingredients**

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

##### **Purposes**

**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**
- 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

##### **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)

**Inactive ingredient** 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)

CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co.  
Artwork No. 6-930840 • A050619 • Made in the USA of US and imported parts • [www.bd.com](http://www.bd.com)

External Use Only  
Professional Use Only



STERILE EO



(01)00354365400372

Package Label-

**BD ChloraPrep Clear**

**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**

**Clear**

REF 930800

NDC 54365-400-37

External Use Only

Professional Use Only

STERILE EO

STERILE SOLUTION

CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co.

Made in the USA of US and imported parts [www.bd.com](http://www.bd.com)

## 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>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg 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:54365-400-37	1 in 1 POUCH	05/24/2019	
1		26 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
-----------	---------------------------------	-----------------	---------------

Category	Citation	Date	Date
NDA	NDA020832	05/24/2019	

**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