ChloraPrep® Clear 3ml 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. To reduce the 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

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 4 in. x 5 in. (130 cm²).
- 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 of the sponge for approximately 30 seconds. Allow solution to air dry for approximately 30 seconds. Do not blot or wipe away.
- **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes of the sponge for approximately 2 minutes. Allow solution to air dry for approximately 1 minute. Do not blot or wipe away.
- if using an ignition source, 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
- call 1-800-523-0502 (M-F 8 a.m.-5 p.m. CST)

**Package/Label Principal Display Panel**
CHLORAPREP ONE-STEP
chlorhexidine gluconate and isopropyl alcohol solution

<table>
<thead>
<tr>
<th>Product Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type</td>
</tr>
<tr>
<td>Route of Administration</td>
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<tr>
<td>Item Code (Source)</td>
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</table>

**Chloraprep® One-Step**

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

**WARNING**

**FLAMMABLE**

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 Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)</td>
<td>CHLORHEXIDINE GLUCONATE</td>
<td>20 mg in 1 mL</td>
</tr>
<tr>
<td>ISO PROPYL ALCOHOL (UNII: ND2M416302) (ISO PROPYL ALCOHOL - UNII:ND2M416302)</td>
<td>ISO PROPYL ALCOHOL</td>
<td>0.7 mL in 1 mL</td>
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### Inactive Ingredients

<table>
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<tr>
<th>Ingredient Name</th>
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<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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### Packaging

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<tr>
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<th>Item Code</th>
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<tr>
<td>1</td>
<td>NDC:54365-400-01</td>
<td>25 in 1 CARTON</td>
<td>07/14/2000</td>
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<tr>
<td>1</td>
<td></td>
<td>1 in 1 POUCH</td>
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<tr>
<td>1</td>
<td></td>
<td>3 mL in 1 APPLICATOR; Type 0: Not a Combination Product</td>
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### Marketing Information

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<td>NDA020832</td>
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**Labeler** - CareFusion 213 LLC (826496312)

**Registrant** - CareFusion 213 LLC (831684456)

**Establishment**

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<tr>
<th>Name</th>
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<td>CareFusion 213 LLC</td>
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<td>826496312</td>
<td>manufacture(54365-400) , analysis(54365-400)</td>
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Revised: 12/2018