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

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**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
PRINCIPAL DISPLAY PANEL-CARTON

3 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)

25 applicators
0.10 fl. oz. (3 ml) each
NDC 054365-400-01
Cat. No. 260400

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

CHLORAPREP ONE-STEP
chlorhexidine gluconate and isopropyl alcohol solution

<table>
<thead>
<tr>
<th>Product Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Type</strong></td>
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<tr>
<td><strong>Route of Administration</strong></td>
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<tr>
<td><strong>Item Code (Source)</strong></td>
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### 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>
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<tr>
<td>ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)</td>
<td>ISOPROPYL ALCOHOL</td>
<td>0.7 mL in 1 mL</td>
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### Inactive Ingredients

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

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
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<th>Marketing End Date</th>
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<tbody>
<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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<tr>
<td>NDA</td>
<td>NDA020832</td>
<td>07/14/2000</td>
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### Labeler - CareFusion 213 LLC (826496312)

### Registrant - CareFusion 213 LLC (831684456)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</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: 6/2019