

NDA 20-832/S-018

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<p>WARNING Flammable</p> <p>Keep away from fire or flame. To reduce risk of fire:</p>  <ul style="list-style-type: none">• solution contains alcohol and gives off flammable vapors• do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin)• avoid getting solution into hairy areas. Solution may take much longer to dry or may not dry completely.• do not allow solution to pool• remove wet material from prep area <p><small>Artwork 6-775425 • Rev. A • Issue Date 12/05</small></p>	<p>Cat No. 260425 NDC #054365-400-10</p> <p>ChloraPrep[®] With Tint</p> <p>Chlorhexidine Gluconate 2% w/v Isopropyl Alcohol 70% v/v • 3.0-mL Applicator Patient Preoperative Skin Preparation</p> <p>External Use Only Professional Use Only. Sterile Contents:* Applicator (1)</p> <p>STERILE EO  Do Not Reuse </p> <p>See Drug Facts for full labeling information</p> <p><small>* Sterility of contents guaranteed unless package is damaged or open.</small></p>
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Cat. No. 260425 NDC #054365-400-10
Single Use • Applicator is STERILE if package is intact

ChloroPrep® With Tint

Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 3.0 mL Applicator

WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

Drug Facts

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

Use for the preparation of the patient's skin prior to surgery

Warnings

For external use only. Flammable, keep away from fire or flame. To reduce the risk of fire:

- solution contains alcohol and gives off **flammable vapors**
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin)
- avoid getting solution into hairy areas. Solution may take much longer to dry or may not dry completely.
- do not allow solution to pool
- remove wet materials from prep area

Do not use

- in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption
- 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

- to reduce the risk of fire the following strategies are recommended:
 - use in a well ventilated area
 - avoid getting solution into hairy areas. If this occurs, wipe hair with towel. Solution may take much longer to dry or may not dry completely.
 - do not allow solution to pool
 - tuck prep towels to absorb solution, and then remove
 - remove wet material from prep area
- maximal treatment area for one applicator is approximately 4 in. x 5 in. (130 cm²). Discard the applicator after a single use.
- pinch the wings on the applicator to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until liquid is visible on the skin.
- **dry surgical sites** (such as abdomen or arm): Use repeated back-and-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately **30 seconds**. Do not blot or wipe away.
- **moist surgical sites** (such as the inguinal fold): Use repeated back-and-forth strokes of the sponge for approximately 2 minutes. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately one **(1) minute**. Do not blot or wipe away.

Other information

- store between 15–30 °C (59–86 °F)
- avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients

- FD&C green #3 dye ■ USP purified water

Questions?

www.chloroprep.com
Call 1-800-523-0502 (M-F 8 a.m.–5 p.m. GST)

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