

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-832**

**FINAL DRAFT PRINTED LABELING**

**ChloraPrep® One-Step**  
**Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v**  
**Patient Preoperative Skin Preparation**  
**3-mL Applicator**

**WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.**  
**DO NOT USE WITH ELECTROCAUTERY PROCEDURES.**

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Chlorhexidine gluconate 2% w/v .....	Antiseptic
Isopropyl alcohol 70% v/v .....	Antiseptic
<b>Use</b>	
<ul style="list-style-type: none"> <li>• for the preparation of the patient's skin prior to surgery</li> </ul>	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>• Flammable, keep away from fire or flame</li> <li>• Do not use with electrocautery procedures</li> <li>• For external-use only</li> </ul>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption</li> <li>• on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol</li> <li>• for lumbar puncture or in contact with the meninges</li> <li>• on open skin wounds or as a general skin cleanser</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>• 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 physician.</li> </ul>	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>• irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</li> </ul>	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• maximum treatment area for one applicator is approximately 130 cm<sup>2</sup> (approx. 4 x 5 in.). Discard the applicator after a single use.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• store between 20–25 °C (68–77 °F) • avoid freezing and excessive heat above 40 °C (104 °F)</li> </ul>	
<b>Inactive ingredients</b> • USP purified water	
<b>Questions?</b> Call 1-800-523-0502 (8 a.m.–5 p.m. CST)	
Medi-Flex Hospital Products, Inc., Overland Park, KS 66210	

Chloraprep® Principal Display Panel-Dispenser Box—NDA No. 20-832

Cat. No. 260400 . . .

**Chloraprep® One-Step**

Chlorhexidine Gluconate 2% (w/v) and Isopropyl Alcohol 70% (v/v)

Antiseptic Patient Preoperative Skin Preparation

Chloraprep® One-Step is a fast-acting, broad spectrum, persistent antiseptic that significantly reduces the number of microorganisms on intact skin.

3-mL Applicator

Single Use

Applicator is sterile if package is intact.

Contents: 1 Each Sponge, Latex Free

Quantity: 1 Box, 25 Each/Box

Store at room temperature 20–25 °C (68–77 °F)

Avoid freezing and excessive heat above 40 °C (104 °F)

APPEAR THIS WAY  
ON ORIGINAL