

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-555

Approved Labeling

Carton Label, Drug Facts, Back Panel

Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 0.67 mL Sepp® Applicator
WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.
DO NOT USE WITH ELECTROCAUTERY PROCEDURES.

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Chlorhexidine gluconate 2% w/v. Antiseptic
Isopropyl alcohol 70% v/v Antiseptic

Use for the preparation of the patient's skin prior to surgery or injection. The maximum treatment area for one applicator is approximately 2.5 by 2.5 inches.

Warnings

Flammable, keep away from fire or flame
Do not use with electrocautery procedures
For external use only

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
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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 physician.

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

- pinch the barrel of the applicator to break the ampule and release the antiseptic. Do not touch the applicator tip. Press the applicator tip 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 applicator 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 applicator 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.
 - discard the applicator after a single use.
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Other information

- store between 20-25 °C (68-77 °F)
 - avoid freezing and excessive heat above 40 °C (104 °F)
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Inactive ingredients USP purified water

Questions? Call 1-800-523-0502 (8 a.m.-5 p.m. CST)

B. Individual Lidding Applicator Label

**ChloraPrep®
Sepp**
Chlorhexidine
Gluconate 2% w/v;
70% Isopropyl
Alcohol v/v
0.67-mL Applicator

**Warning.
Flammable.
Keep away from
fire or flame.
Do not use with
electrocautery
procedures.
Applicator sterile
unless seal is
broken.**

**Medi-Flex, Inc.
Overland Park, KS**

**Lot No:
Exp.:**

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Janice Soreth
10/4/02 03:59:38 PM

Charles Ganley
10/7/02 11:03:01 AM