

NDA No. 20-832, Chlorhexidine Gluconate 2% (w/v) Topical Solution
CBE in 30 Days Supplement No. 002, October 2001

Volume 1
Page 10

Front Panel - Labeling Format (100%) for Chloraprep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 1.5-mL Frepp Applicator

REVISED 9/13/01

cat. No. 260299

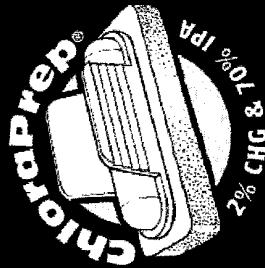
Chloraprep® One-Step Frepp® Applicators

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.

1.5-mL Frepp® Applicator
Single Use

Applicator is **sterile** if package is intact
Contents: 1 Each Sponge, Latex-Free
Quantity: 1 Box, 20 Each/Box

Store at room temperature 20-25 °C (68-77 °F)
Avoid freezing and excessive heat above 40 °C (104 °F)



MEDIFLEX HOSPITAL PRODUCTS, INC.
Overland Park, KS 66210-2129
1-800-523-0502

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Volume 1
 Page 11

Back Panel - Labeling Format (100%) for ChloroPrep® One-Step
 Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
 Patient Preoperative Skin Preparation • 1.5-mL Frepp Applicator
 REVISED 9/13/01

▲ Tear at perforation for easy dispensing ▲

ChloroPrep® One-Step Frepp® Applicators

Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v • Patient Preoperative Skin Preparation • 1.5-mL Frepp® Applicator

Drug Facts

Active ingredients
 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

- 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 lumbur 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 physician.
- Stop use and ask a doctor if** irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Drug Facts (continued)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- pinch the wings on the applicator to break the ampule and release the antiseptic. Do not touch 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 applicator for approximately **30 seconds**. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately 2 minutes.
- **most 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. ■ maximum treatment area for one applicator is approximately 42 cm² (approx. 2.5 x 2.5 in.). Discard the applicator after a single use.

Other information ■ store between 20–25 °C (68–77 °F)
 ■ avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients USPurified water

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

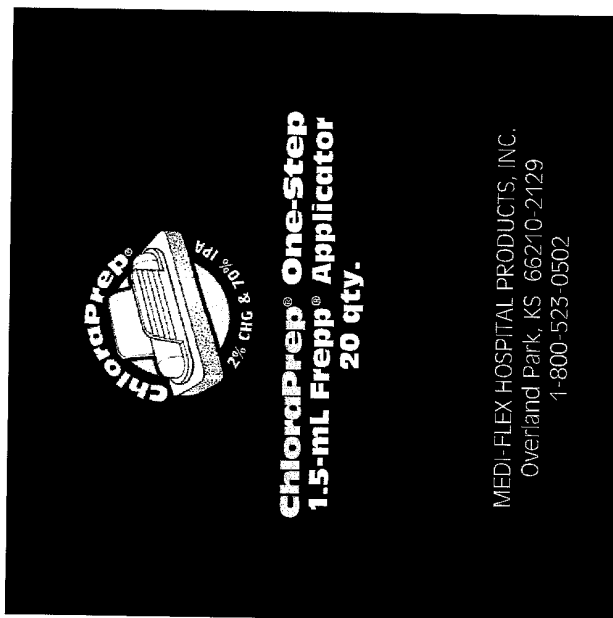
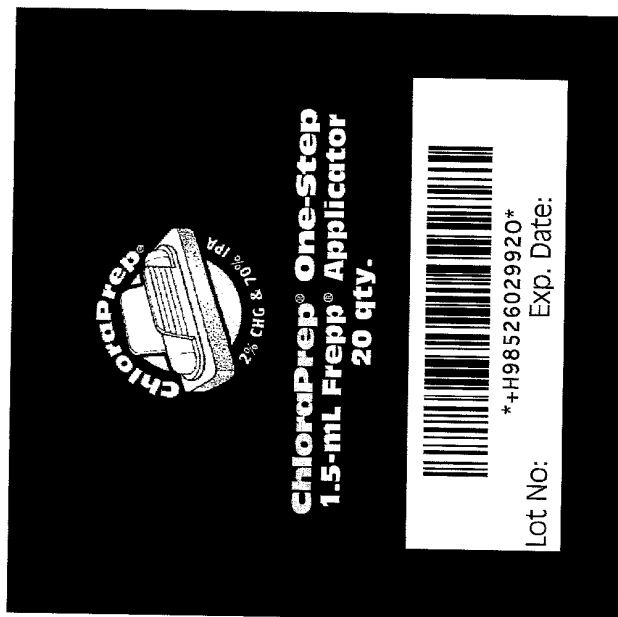
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 Headings: 8 pt helvetica bold italic, left justified
 Subheadings: 6 pt helvetica bold, left justified
 Body Text: 6 pt helvetica regular, 6.5 leading, left justified
 2.5 point box barline
 2.5 point barline

NDA No. 20-832, Chlorhexidine Gluconate 2% (w/v) Topical Solution
CBE in 30 Days Supplement No. 002, October 2001

Volume 1
Page 12

Side Panels - Labeling Format (100%) for ChloroPrep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 1.5-mL Frepp Applicator

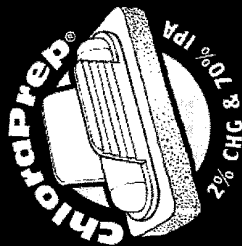


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CBE in 30 Days Supplement No. 002, October 2001

Volume 1
Page 13

Top Panel - Labeling Format (100%) for Chloraprep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 1.5-mL Frepp Applicator

▲ Tear at perforation for easy dispensing ▲



Chloraprep® One-Step
1.5-mL Frepp® Applicator
20 qty.

NDA No. 20-832, Chlorhexidine Gluconate 2% (w/v) Topical Solution
CBE in 30 Days Supplement No. 002, October 2001

Volume 1
Page 14

Individual Lidding - Labeling Format (100%) for ChlorPrep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 1.5-mL Frepp Applicator

REVISED 8/6/01

Exp. Date
Lot No.

Cat. No. 260299
**ChlorPrep® One-Step
Frepp Applicator**
Chlorhexidine Gluconate 2% (w/v)
and Isopropyl Alcohol 70% (v/v)
Patient Preoperative Skin Preparation
1.5-mL Frepp Applicator

Single Use • Latex Free
WARNING - FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.
DO NOT USE WITH ELECTROCAUTERY PROCEDURES.

APPLICATOR STERILE UNLESS SEAL IS BROKEN
Medi-Flex Hospital Products, Inc. • Overland Park, KS 66210

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/s/

Linda Katz
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