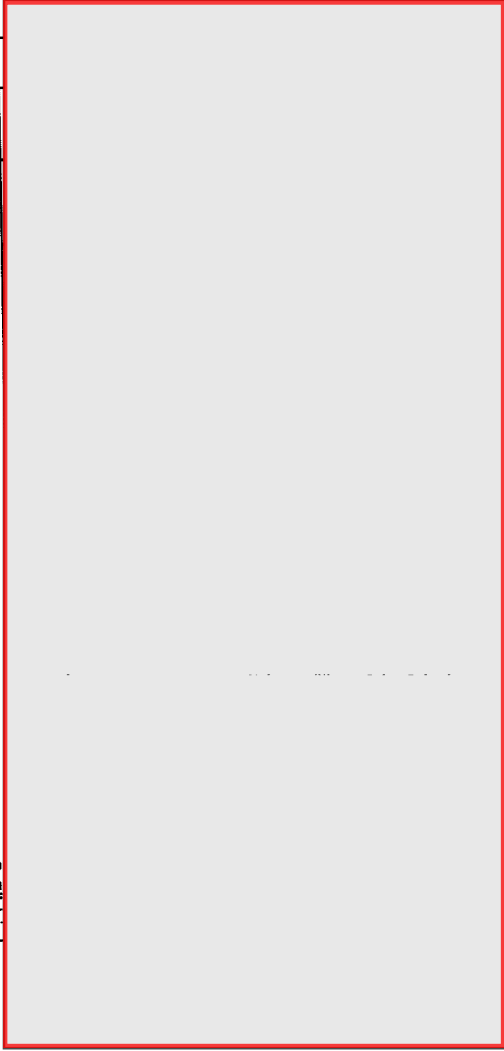


Part # 6-786800

26-mL ChloraPrep Applicator Lidding



FPO
 DOES NOT PRINT
 DASHED BOX ONLY REPRESENTS
 LIVE AREA

Cat. No. 260800 NDC #054365-400-05 DIN #02160757

ChloraPrep[®]
With Tint

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

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

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**
- Solution contains alcohol and gives off flammable vapors while drying - allow to dry 3 minutes on skin
 - Do not use with electrocautery procedures
 - Do not allow to solution to pool
 - Remove solution-soaked 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 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

- **Maximal treatment area for one applicator is approximately 1126 cm² (approx. 13.2 in. x 13.2 in.). 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 **three (3) minutes**. 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 **three (3) minutes**. Do not blot or wipe away.

Other information

- Store between 20–25 °C (68–77 °F)
- Avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients ■ USP purified water
 ■ Pledget contains FD&C green #3 dye

Questions?

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

Single Use
 Applicator is STERILE if package is intact

Medi-Flex, Inc.
 Leawood, KS 66211

2.35" wide

Ingredients:.....
 6 pt AntiqueOlive Bold

Title:
 14 pt helvetica black oblique

Headings:
 8 pt helvetica black oblique,
 left justified

0.5 point hairline

Subheadings:
 6 pt helvetica
 black,
 left justified

Bullet:
 5 pt zapf
 dingbats,
 solid square

9.5" high

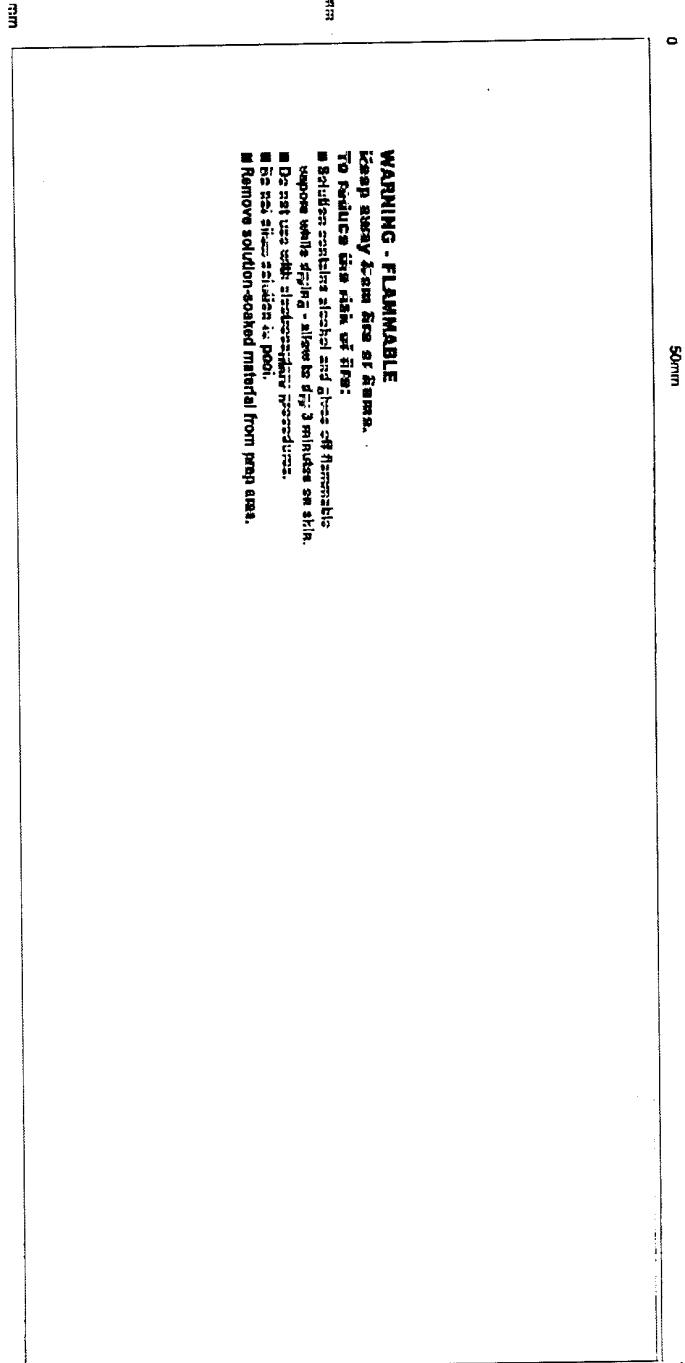
2.5 point
 box barline

Body Text:
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 regular,
 6.5 leading,
 left justified

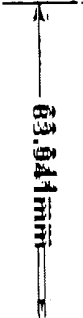
heading:
 8 pt helvetica
 black oblique

text:
 6 pt helvetica
 black

8-100880
26ml Chloragreg With Tint Applicator Cilaha Film

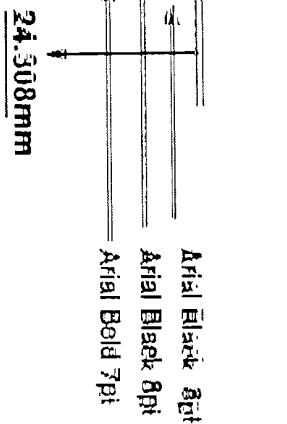


WARNING - FLAMMABLE
Keep away from fire or flame.
To reduce the risk of fire:
■ Solution contains alcohol and other off-flammable vapors while drying - allow to dry 3 minutes on skin.
■ Do not use with alcohol-based products.
■ Do not use solution in pool.
■ Remove solution-soaked material from prep area.



83.94 mm

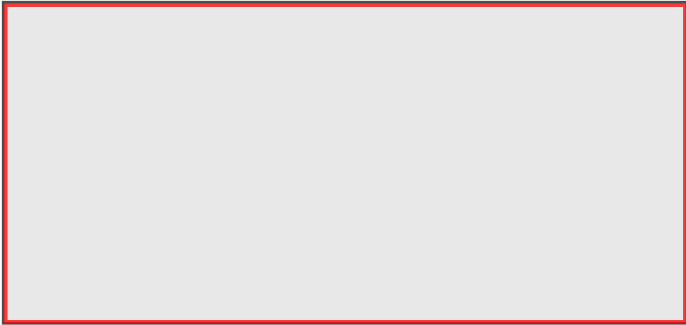
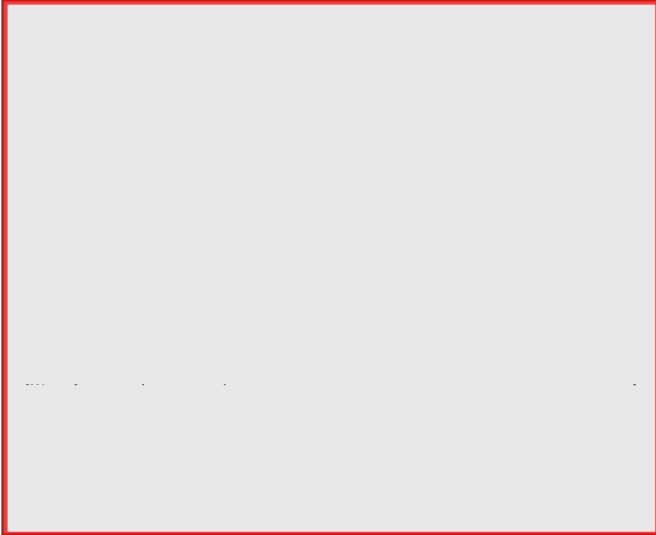
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24.308 mm

This label is 83.94 mm high and 24.308 mm wide. The edges of the label are 3.175 mm from the edges of the box. The label is oriented vertically and horizontally. NOTE: Text box center points both vertically and horizontally are used to place the text box in correct position.

Part # 6-775800 insert
Insert Sheet - Labeling Format (100%) for ChloroPrep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 26-ml Applicator



6" wide

Numbers:
9 pt antique olive roman Title
18 pt antique olive bold
Heading:
10 pt antique olive roman
Formulation:
9 pt antique olive roman
Body Text:
8 pt Cl Helvetica Condensed

Cat. No. 260800 NDC 054365-000-05 DIN 02160757

ChloroPrep® With Tint

Patient Preoperative Skin Preparation

Chlorhexidine Gluconate 2% (w/v) • Isopropyl Alcohol 70% (v/v) • 26-ml Applicator

STERILE

External Use Only Professional Use Only

Seal/Contents *
Applicator (1)
Cotton Swabs (2)

Lot No.: Exp. Date:

* Sterility of contents guaranteed unless package is damaged or open.

See Drug Facts for full drug labeling information

WARNING	
	<ul style="list-style-type: none">ChloroPrep solution contains alcohol and is flammable while drying.Do not use with electrocautery procedures.

Medi-Flex recommends all users participate in a product in service training prior to use. In-service training is available from your Medi-Flex sales representative.

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

To Prevent Fire

- Do not use with electrocautery procedures.
- Do not drape until prepared area is completely dry.
- Allow preparation to completely dry:
 - if the prepped area is to be extended, or
 - if grapping for an additional procedure, or
 - if re-application of skin preparation is required.
- drying time for dry surgical sites is approximately three (3) minutes.
- drying time for moist surgical sites is approximately three (3) minutes.

• Whenever grapping the neck area, place towels under each side to absorb excess solution. Remove the towels before draping.

- Do not allow the solution to pool.
- Remove any soiled drapes, gowns, and gloves before draping.
- Avoid getting preparation into hair. If solution gets into hair, wipe hair with towel and allow some time for solution to completely dry.

Directions for Use:
Prepare Patient for ChloroPrep Solution:

- When hair removal is necessary, the preferred method is to use a surgical clipper on the morning of the surgery.
- Preparation should be applied to clean, dry, residue-free, intact skin.
- When applying the solution, start at the incision site and apply the solution in a back and forth or up and down motion.

After ChloroPrep is Applied:

- Allow solution to completely dry prior to draping.

While Waiting for ChloroPrep to Dry:

- Do not drape.
- Check for pooled preparation. Use sterile gauze to absorb pooled solution. Do not blot. Allow solution to dry.
- Remove all solution-soaked materials.

When ChloroPrep Solution is Dry:

- Begin draping only after solution is dry and all solution-soaked materials are removed.
- If incision drapes are used, apply directly to dry prepped area.

Questions or Comments?

- (800) 523-0602 (M-F 8 a.m. - 5 p.m. CST) • www.chloroprep.com

Statement
9 pt Cl Helvetica
Condensed

6" high

Sub heading:
8 pt antique olive roman
Bullet:
8 pt Round Cl Helvetica Condensed

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

/s/

Curtis Rosebraugh
5/3/05 02:21:50 PM