

Artwork No. 6-787800, 26-mL ChloroPrep One-Step Applicator Lidding

- PMS 2746 C Blue
- PMS 185 C Red
- Black

Date	Rev	CAF #	
4/17/06	A	2006-04-07	Creation
10/06	B	TBD	What was changed

FPO
DOES NOT PRINT
DASHED BOX ONLY REPRESENTS
LIVE AREA

Cat. No. 260800 NDC #054365-400-14

ChloroPrep[®] one-Step
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.

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 risk of fire:

- do not use 26-mL applicator for head and neck surgery
- do not use on an area smaller than 8.4 in. x 8.4 in.
- Use a small applicator instead
- 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

- before using this product see insert for important information
- to reduce the risk of fire the following strategies are recommended:
 - at the end of prep, discard any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount available.
 - 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 materials from prep area
 - drape after solution is completely dry
- Maximal treatment area for one applicator is approximately 13.2 in. x 13.2 in. (1126 cm²). Discard the applicator after a single use.
- pinch the wing 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 15–30 °C (59–86 °F)
- Avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients

- USP purified water

Questions? www.chloroprep.com
Call 1-800-523-0502 (M-F 9 a.m.–5 p.m. CST)

Single Use
Applicator is STERILE if package is intact
Enturia, Inc.
Leawood, KS 66211

Artwork No. 6-787800 • Rev. B • Issue Date: 10/06

Cat. No., etc. -
6 pt Helvetica, Bold
Center Justified

'One-Step' -
11.5 pt Antique Olive Nord
Center Justified

Formulation, "Patient Preoperative..." and "26-mL..." -
6.25 pt Antique Olive Roman, Bold,
Center Justified

Warning Statements -
7 pt Antique Olive Roman, Bold,
Center Justified

Drug Facts Box:

Title -
14 pt Helvetica-Black, Oblique,
Left Justified

Headings -
8 pt Helvetica-Black, Oblique,
Left Justified

Subheadings -
6 pt Helvetica-Black,
Left Justified

Body Text 6 pt Helvetica,
5.8 pt leading
Left Justified

"Bolted" Body Text -
6 pt Helvetica-Black

Hairline -
0.5 pt

Box barline -
2.5 pt

Bullets -
5 pt Zap/Dingbats, Solid Square

"Call" and days/time Statement -
6 pt Helvetica 95 Black, Oblique
Left Justified

Phone number -
6 pt Helvetica, Oblique

"Single Use" and Sterility Statement -
8 pt Helvetica,
Center Justified

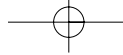
Enturia information -
7 pt Antique Olive Roman, Bold,
Center Justified

Artwork No., etc. -
6 pt Helvetica-Condensed-Light
Center Justified

Leading -
5.8 pt

9.5" high

2.35" wide



Artwork No. 6-776800, 26-mL ChloroPrep One-Step Applicator insert

- PMS 2746 C Blue
- Process Black
- Process Red

Date	Rev	CAF #	What was changed
4/17/06	A	2006-04-07	Creation
6/28/06	B	2006-06-36	Removed "Lot No.: and Exp. Date:" legend.
10/06	c	2006-10-xx	redistribution of info. to accommodate new warnings and usage of product

Artwork area 6" w

- Warning-**
11 pt antique olive roman **Bold**
- Flammable-**
8 pt antique olive roman **Bold**
- Cat. No. etc. -**
9 pt Antique Olive Roman,
Center Justified
- 'One-Step' -**
13 pt Antique Olive Nord
- Formulation and "Patient
Preoperative..." -**
9 pt & 13pt Antique Olive Roman,
Center Justified
- "STERILE", "EO", "Do Not Reuse"
and "Sterility of contents
guaranteed ..."** -
8 pt Helvetica-Condensed-Light
- "External Use Only", "Professional
Use Only", and "Sterile Contents:"
Applicator (1)" -**
9 pt Helvetica-Condensed-Light
- Lot No. and Exp. Date -**
8 pt Helvetica-Condensed-Bold
- "See Drug Facts for full drug ..."** -
8 pt Helvetica-Condensed-Black, **Bold**
- Body Text and Artwork info -**
7 pt Helvetica-Condensed-Light
- Subheading -**
7 pt Antique Olive Roman
- Bullets -**
7 pt Round Helvetica-Condensed-Light

WARNING

Flammable

Keep away from fire or flame. To reduce risk of fire:

- do not use 26-mL applicator for head and neck surgery.
- do not use on an area smaller than 8.4 in. x 8.4 in. Use a small applicator instead.
- 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

See Drug Facts for full labeling information

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

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

To Reduce Risk of Fire:

- Do not drape or use ignition source (e.g. cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin)
- Allow preparation to completely dry:
 - if the preparation area is to be extended, or
 - if prepping for an additional procedure, or
 - if re-application of skin preparation is required.
- drying time for dry surgical sites (such as abdomen or arm) is approximately **three (3) minutes**.
- drying time for moist surgical sites (such as inguinal fold) is approximately **three (3) minutes**.

- Whenever prepping the neck area, place towels under each side to absorb excess solution.
- Do not allow the solution to pool.
- Remove any wet materials, drapes and gowns before draping.
- 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.

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.

Cat No. 260800 NDC #054365-400-14

**ChloroPrep[®]
One-Step**

Chlorhexidine Gluconate 2% w/v
Isopropyl Alcohol 70% v/v • 26-mL Applicator

Patient Preoperative Skin Preparation

STERILE

EO

External Use Only
Professional Use Only

Sterile Contents:*
Applicator(1)
Cotton Swabs (2)

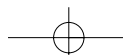
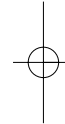
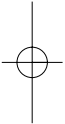
Do Not Reuse

Do Not Reuse

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

Artwork No. 6-776800 • Rev. C • Issue Date: 10/06

Artwork area 6" h



Part No. 6-774800
 26-mL ChloraPrep One-Step Applicator Body Label

Date	Revision	CAF	Description of Change
10/06	A	2006-xx-xx	Create

- PMS 2746 C Blue
- PMS 185 C Red
- Black

Label Content

