

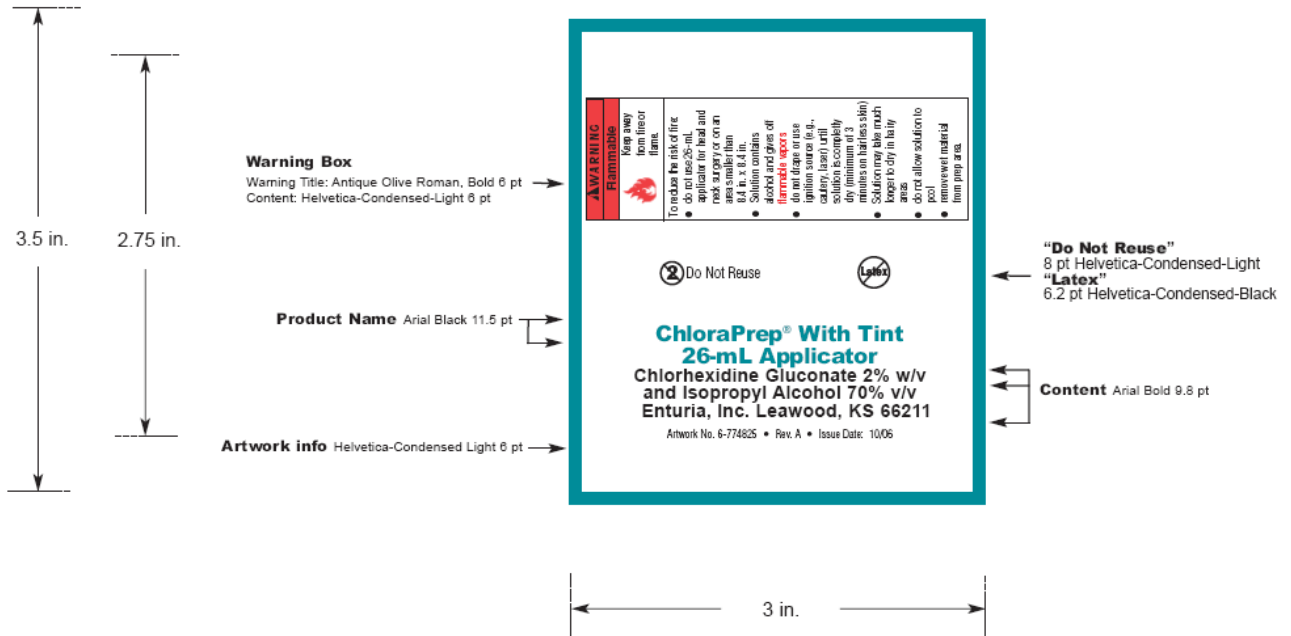
NDA 20-832/S-016
 Page 4

Part No. 6-774825
 26-mL ChloroPrep With Tint Applicator Body Label

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

- PMS 321 C Teal
- PMS 185 C Red
- Black

Label Content



Part # 6-775825
 Insert Sheet - Labeling Format (100%) for ChloroPrep® With Tint
 Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
 Patient Preoperative Skin Preparation • 26-mL Applicator

Date	Rev	CAF #	What was changed
8/25/05	A	2005-08-17	Create.
10/06	B	TBD	xxx

6" wide

Warning:
 8 pt antique olive
 roman **Bold**

Numbers:
 9 pt antique olive
 roman

Title:
 19 pt antique
 olive nord

Heading:
 13pt antique olive roman

Formulation:
 9 pt antique olive
 roman

Body Text:
 7 pt CI Helvetica
 Condensed

Sub heading
 7 pt antique olive
 roman

Bullet:
 7 pt Round CI
 Helvetica
 Condensed

<div style="background-color: red; color: white; text-align: center; padding: 2px;">WARNING</div> <div style="background-color: red; color: white; text-align: center; padding: 2px;">Flammable</div> <p>Keep away from fire or flame. To reduce risk of fire:</p> <ul style="list-style-type: none"> 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 <p style="text-align: center; font-weight: bold; font-size: 0.8em;">See Drug Facts for full labeling information</p> <p style="font-size: 0.7em;">Enturia recommends all users participate in a product in-service training prior to use. In-servicing is available from your Enturia sales representative.</p> <p style="font-size: 0.7em;">ChloroPrep is a fast-acting, broad spectrum, persistent antiseptic that significantly reduces the number of microorganisms on intact skin.</p> <p style="font-size: 0.7em;">To Reduce Risk of Fire:</p> <ul style="list-style-type: none"> Do not use ignition source (e.g. cautery, laser) until product is completely dry (minimum of 3 minutes on hairless skin) Allow preparation to completely dry: <ul style="list-style-type: none"> - 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 is approximately three (3) minutes. - drying time for moist surgical sites is approximately three (3) minutes. <ul style="list-style-type: none"> Whenever prepping the neck area, place towels under each side to absorb excess solution. Do not allow the solution to pool. Remove wet towels, drapes, and gowns before draping. Avoid getting solution into hair. If this occurs, wipe hair with towel. Solution may take much longer to dry or may not dry completely. <p style="font-size: 0.7em;">Directions for Use:</p> <p style="font-size: 0.7em;">Prepare Patient for ChloroPrep Solution:</p> <ul style="list-style-type: none"> 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. 	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Cat No. 260825</td> <td style="width: 50%;">NDC #054365-400-05</td> </tr> <tr> <td colspan="2" style="text-align: center;"> </td> </tr> <tr> <td colspan="2" style="text-align: center;"> Chlorhexidine Gluconate 2% w/v Isopropyl Alcohol 70% v/v • 26-mL Applicator Patient Preoperative Skin Preparation </td> </tr> <tr> <td style="border: 1px solid black; padding: 2px;">STERILE</td> <td style="border: 1px solid black; padding: 2px;">EO</td> </tr> <tr> <td style="text-align: center;"> Do Not Reuse </td> <td style="text-align: center;"> External Use Only Professional Use Only </td> </tr> <tr> <td colspan="2" style="text-align: right;"> Sterile Contents:* Applicator(1) Cotton Swabs (2) </td> </tr> <tr> <td colspan="2" style="font-size: 0.8em;">* Sterility of contents guaranteed unless package is damaged or open.</td> </tr> </table> <p style="font-size: 0.8em;">After ChloroPrep is Applied:</p> <ul style="list-style-type: none"> Allow solution to completely dry prior to draping. <p style="font-size: 0.8em;">While Waiting for ChloroPrep to Dry:</p> <ul style="list-style-type: none"> Do not drape. Check for pooled preparation. Use sterile gauze to absorb pooled solution. Do not blot. Allow solution to dry. Remove all wet materials. <p style="font-size: 0.8em;">When ChloroPrep Solution is Dry:</p> <ul style="list-style-type: none"> Begin draping only after solution is dry and all solution-soaked materials are removed. If incise drapes are used, apply directly to dry prepped area. <p style="font-size: 0.8em;">How to remove ChloroPrep with Tint:</p> <ul style="list-style-type: none"> It is recommended that ChloroPrep with Tint remain on the skin, especially at the incision site, post procedure, to provide continued antimicrobial activity. The tint will slowly fade from the skin. If removal is necessary for surgical site cleansing after stitching, remove with soap and water, alcohol, or a ChloroPrep untinted applicator. <p style="font-size: 0.8em;">Questions or Comments?</p> <ul style="list-style-type: none"> (800) 523-0502 (M-F 8 a.m.-5 p.m. CST) www.chloroprep.com <p style="text-align: right; font-size: 0.8em;">Artwork No. 6-775825 • Rev. B • Issue Date: 10/06</p>	Cat No. 260825	NDC #054365-400-05			Chlorhexidine Gluconate 2% w/v Isopropyl Alcohol 70% v/v • 26-mL Applicator Patient Preoperative Skin Preparation		STERILE	EO	Do Not Reuse	External Use Only Professional Use Only	Sterile Contents:* Applicator(1) Cotton Swabs (2)		* Sterility of contents guaranteed unless package is damaged or open.	
Cat No. 260825	NDC #054365-400-05														
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Do Not Reuse	External Use Only Professional Use Only														
Sterile Contents:* Applicator(1) Cotton Swabs (2)															
* Sterility of contents guaranteed unless package is damaged or open.															

Statement:
 9 pt CI Helvetica
 Condensed

6" high

Artwork Part No. 6-786825

26-mL ChloroPrep with Tint Applicator Lidding

- PMS 321 C Teal
- PMS 185 C Red
- Black

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

'With Tint' -
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 (except for Isopropyl alcohol active ingredient) -
6 pt Helvetica, 5.8 pt leading
Left Justified

"Isopropyl alcohol..." (under Active Ingredients) -
6 pt Helvetica, Bold, Oblique

"Bolder" Body Text -
6 pt Helvetica-Black

Headline -
0.5 pt

Box barline -
2.5 pt

Bullets -
5 pt ZapDingbats, 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

FPO
DOES NOT PRINT
DASHED BOX ONLY REPRESENTS
LIVE AREA

Cat. No. 260825 NDC #054365-400-05



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 product 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

- **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.**
- 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 material from prep area
- drape after solution is completely dry
- 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

- FD&C green #3 dye
- USP purified water

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

Single Use
Applicator is STERILE if package is intact

Enturia, Inc.
Leawood, KS 66211

Artwork No. 6-786825 • Rev. D • Issue Date: 10/06

9.5" high

2.35" wide

Date	Rev	CAF #	Creation
8/15/05	A	2005-08-12	Reduced the distance between the Drug Facts box and the Single Use sentence to center artwork within print area and chevron; included additional font type and size statements (no artwork changes.)
11/02/05	B	2005-11-03	Removed blank space between the ChloroPrep logo and the statement 'With Tint' (no changes to artwork content were made.)
11/28/05	C	2005-11-54	Change Store Temperature from 20-25C (68-77F) to 15-30C (59-86F); added artwork p/n, rev., and issue date; font specs detailed; per FDA recommendation, in the Drug Facts box, the following were modified: under Warnings, 'For external use only.' was moved in front of 'Flammable: Keep away from fire or flame,' flammability statement; a period was added
10/06	D	TBD	

What was changed

Date	Rev	CAF #	Creation
			at the end of the statement, the comma was replaced with a colon and first letter of 'keep' was changed to upper case; under 'When using this product...' the word physician was replaced with 'doctor'; under Questions, the first letter of 'call' was made lower case and made web address first item in this section; removed "Do not use with electrocautery procedures." from heading and from Warnings; under Warnings, all seven bulleted statements were revised per FDA recommendation; under 'Directions', bulleted information was inserted between the first and second bullet in this section ('to reduce the risk of fire...') per FDA recomm; the ChloroPrep logo was replaced with scrub teal logo and 'With Tint' color changed to PMS 321C; under 'Inactive Ingredients', 'Pledget contains' was deleted and "USP purified..." bullet as moved below the FD&C bullet; removed DIN number.
10/06	D	TBD	

What was changed