6-824100 ChloraPrep Swabstick Carton

Date	Rev	CAF #	What Was Changed
05/27/04	A	2004-05-41	Creation
8/17/04	B	2004-08-27	revise product name on top panel (add "Single") for consistency with other panels, delete "Antiseptic" from "Patient Preoperative..." statement on top and front panel for consistency with back panel and other packaging components, move "Do not use with" down to next line (on back panel) so complete statement is on one line
9/4/04	C	2004-09-06	in Drug Facts box, revise treatment area, revise dry times from "at least" to "approximately"
10/4/04	D	2004-10-05	Top panel - add "Antiseptic" to "Patient Preoperative...", delete "s" from "Applicator"; back panel - delete parentheses from "w/v" and "v/v", in Drug Facts box, revise treatment area to 2.5 x 2.5 inches and delete metric measurement, modify verbiage in "Directions" section to more closely match Sepp carton labeling, in "Questions" section reverse order of web address and phone no.; side panel - add MF logo, add varnish cut-out for lot/exp.; front panel - add "Antiseptic" to "Patient Preoperative...", moved volume to "Single Swabstick Applicator" from "Contents" statement, add bullet to name/location, revise logo to white outline; side panel - add MF logo - all revisions made for consistency with Sepp carton
05/10/05	E	2005-04-67	Revise statement "Antiseptic Patient Preoperative Preparation" to "Patient Preoperative Skin Preparation" on Top and Front Panel. Under 'Directions', in Drug Facts box, removed period after the word 'use' on the last bullet and revised and combined the wording of the external use and flammability statement to "For external use only. Flammable: keep away from fire or flame." - as requested by FDA
10/3/06	F	2006-09-34	Change Co. Logo and Name from Medi-Flex to Enturia Inc. Included color swatches next to color legends, revised artwork legend on inner flap. Revise title of document to be consistent with raw material specification title.
02/07	G	TBD	Remove "Do not use with electrocautery procedures." from back panel and from Warnings; ; under 'Directions', bulleted information was inserted as the first bullet in this section ('to prevent fire..."); under 'Other Information', "avoid freezing..." was made a separate line; under 'Questions', web address was made a separate line; per FDA recommendation, in the Drug Facts box, the following were modified: under Warnings, 'For external use only. Flammable: Keep away from fire or flame' was bulleted; the word '(continued)' in the second column was unbolded and unitalicized; under 'When using this product...' the word physician was replaced with 'doctor'; under Questions, the first letter of 'call' was made lower case and the word was unbolded, web address was unbolded and bulleted. Added new warning table to front panel. Remove "#" symbol from next to NDC. change temperature of storage from "20-25° C" to "15-30°F"

1

1½

2 47/64

Indicates varnish cut-out area

NO VARNISH

Colors
Pantone 2746 C blue
Pantone 3248 C blue (blend color)
Pantone 109 C yellow
Pantone 186 C red

Artwork No. 6-824100 Rev. G
Issue Date:02/07

ChloraPrep® Single Swabstick Applicator
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation

▼ Tear Here ▼

ChloraPrep® Single Swabstick
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • Single Swabstick 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 or injection.

Warnings
For external use only. Flammable, keep away from fire or flame. To reduce risk of fire:
- 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 all 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.

▶

Drug Facts (continued)

Directions
- to reduce risk of fire the following strategies are recommended:
  - 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
- maximal treatment area for one applicator is approximately 2.5 in. x 2.5 in. (42 cm²). Discard the applicator after a single use.
- tear pouch at side notch to reveal applicator handle. Do not touch foam applicator tip. Place foam flat side down on the treatment area.
- **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.

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

enturia™

ChloraPrep® Single Swabstick Applicators
48 qty.

+H98526010025

Lot No: NO VARNISH
Exp. Date: NO VARNISH

Cat. No. 260100 **NDC 054365-400-07**

ChloraPrep® Single Swabstick Applicators

Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v

Patient Preoperative Skin Preparation

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

1.75-mL Single Swabstick Applicator

Single Use

Contents: 1 Each Applicator, Latex-Free

Quantity: 1 Box, 48 Each/Box
Store at room temperature 15-30 °C (59-86 °F)
Avoid freezing and excessive heat above 40 °C (104 °F)

Enturia, Inc. • Leawood, KS 66211

⚠WARNING
Flammable
Keep away from fire or flame.
To reduce risk of fire:
- 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

ChloraPrep® IPA 70% 2% CHG

enturia™

enturia™

ChloraPrep® Single Swabstick Applicators
48 qty.

Enturia, Inc.
Leawood, KS 66211
1-800-523-0502
www.chloraprep.com

Fonts Descriptions

Product name	Antique Olive Nord 10pt
Product Description	Antique Olive Compact 8pt
Warning statements in red	Antique Olive Black 8pt
"Drug Facts"	LBI Helvetica Black 14pt
Headings (i.e. "Active Ingredients)	LBI Helvetica Black 8pt
Subheadings (i.e. "Do not use")	LB Helvetica Black 6pt
"flammable vapors"	LB Helvetica Bold 6pt -186 C Red
"regular" body text	Helvetica 6pt
bullets	Zapf Dingbats 5pt
"Drug Facts (2nd panel)	LBI Helvetica Black 8pt
"(continued)"	Helvetica 8pt

Fonts Descriptions

Product name	Antique Olive Nord 20pt
quantity	Antique Olive Nord 15pt

Fonts Descriptions

Product name	Antique Olive Nord 20pt
Product Description	Antique Olive Compact 10pt
"Antiseptic Patient..."	Antique Olive Black 10pt
"ChloraPrep is a broad spectrum..."	Antique Olive Black 9pt
"Single Swabstick...", "Contents", "Qty"	Antique Olive Bold 9pt
"Regular" font text	Antique Olive Roman 9pt

Fonts Descriptions

Product name	Antique Olive Nord 20pt
quantity	Antique Olive Nord 15pt
Address info	Antique Olive Bold 10pt