Front Panel - Labeling Format (100%) for ChloraPrep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 10.5-mL Applicator

REDUCED 65% TO FIT

CREATED 5/01/02 REVISED 6/10/02 REVISED 8/20/02 REVISED 1/30/03
REVISED 2/3/03 (annotations) REVISED 2/11/03 REVISED 2/13/03 REVISED 2/17/03

Numbers: 14 pt antique olive compact

Title: 40 pt antique olive nord

Formulation: 15 pt antique olive compact

Statement: 18 pt antique olive compact

Applicator: 15 pt antique olive bold

Single use: 15 pt antique olive roman

Applicator, etc.: 15 pt antique olive bold "Sterile" 15 pt antique olive nord

Storage, etc.: 15 pt antique olive roman

**Cat. No. 260700 NDC #054365-400-04 DIN#02160757**

# ChloraPrep® One-Step

**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.**

10.5-mL Applicator

Single Use

Applicator is **sterile** if package is intact

Contents: 1 Each Sponge, Latex Free
Quantity: 1 Box, 25 Each/Box

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

MEDI-FLEX®

Back Panel - Labeling Format (100%) for ChloraPrep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 10.5-mL Applicator

REDUCED 65% TO FIT

CREATED 5/01/02 REVISED 6/10/02 REVISED 8/20/02 REVISED 1/30/03 REVISED 2/3/03 (annotations)
REVISED 2/11/03 REVISED 2/13/03 REVISED 2/17/03

Title: 14 pt helvetica bold italic

Headings: 8 pt helvetica bold italic, left justified

Subheadings: 6 pt helvetica bold, left justified

0.5 point hairline

2.5 point barline

2.5 point box barline

Bullet: 5 pt zapf dingbats, solid square

Body Text: 6 pt helvetica regular, 6.5 leading, left justified

# ChloraPrep® One-Step

**Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v**
**Patient Preoperative Skin Preparation • 10.5-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.** Do not use with electrocautery procedures.

**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**
- 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 30 seconds. 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 one (1) minute. Do not blot or wipe away.
- maximal treatment area for one applicator is approximately 457 cm² (approximately 8.4 x 8.4 inches). 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** USP purified water

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

MEDI-FLEX®

Side Panels - Labeling Format (100%) for ChloraPrep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 10.5-mL Applicator

REDUCED 65% TO FIT

CREATED 5/01/02 REVISED 6/10/02 REVISED 8/20/02 REVISED 1/30/03 REVISED 2/3/03 (annotations)
REVISED 2/11/03 REVISED 2/13/03 REVISED 2/17/03

MEDI-FLEX®

**ChloraPrep® One-Step**

**10.5-mL Applicators • 25 qty.**

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

MEDI-FLEX®

**ChloraPrep® One-Step**

**10.5-mL Applicators • 25 qty.**

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

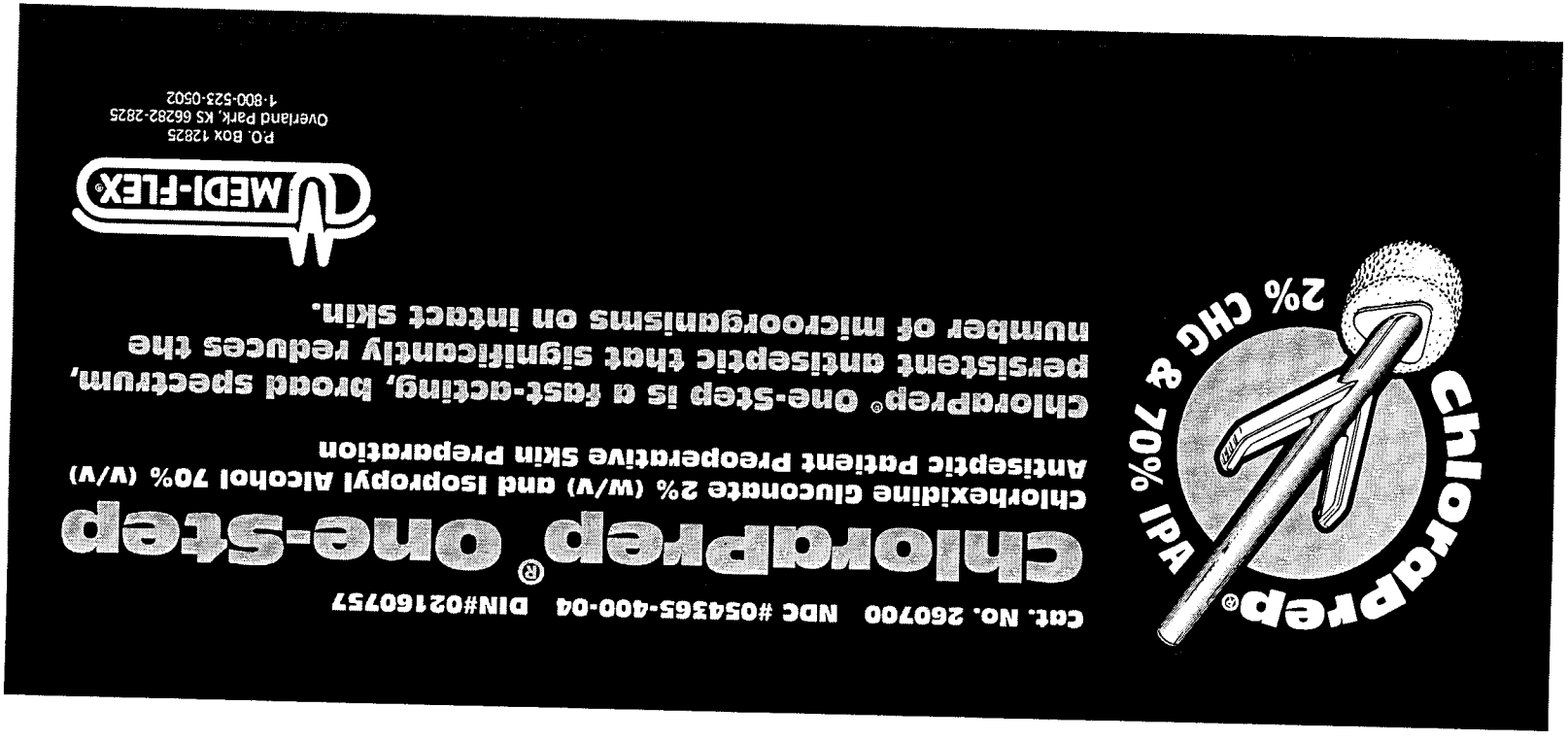
*+H9852607002B*

Lot No: Exp. Date:

Top Panel - Labeling Format (100%) for ChloraPrep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 10.5-mL Applicator

REDUCED 65% TO FIT

CREATED 5/01/02 REVISED 6/10/02 REVISED 8/20/02 REVISED 1/30/03 REVISED 2/3/03 (annotations)
REVISED 2/11/03 REVISED 2/13/03 REVISED 2/17/03



Lidding artwork - Labeling Format (100%) for ChloraPrep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 10.5-mL Applicator

CREATED 5/01/02 REVISED 6/10/02 REVISED 8/20/02 REVISED 1/30/03 REVISED 2/3/03
(annotations) REVISED 2/11/03 REVISED 2/13/03 REVISED 2/17/03

immediate container labeling

Cat. No. 260700 NDC #054365-400-04 DIN#02160757

# ChloraPrep® One-Step

Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 10.5mL Applicator

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

Title: 14 pt helvetica bold italic

Headings: 8 pt helvetica bold italic, left justified

0.5 point hairline

Subheadings: 6 pt helvetica bold, left justified

Bullet: 5 pt zapf dingbats, solid square

## Drug Facts

**Active Ingredients** — **Purpose**
Chlorhexidine gluconate 2% w/v ..... Antiseptic
Isopropyl alcohol 70% w/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.** Do not use with electrocautery procedures.

**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**
- 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 30 seconds. 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 one (1) minute. Do not blot or wipe away.
- maximal treatment area for one applicator is approximately 457 $cm^2$ (approximately 8.4 x 8.4 inches). 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**
- USP purified water

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

2.5 point barline

2.5 point box barline

Body Text: 6 pt helvetica regular, 6.5 leading, left justified

Single Use
Applicator is **sterile** if package is intact

Lot No: Exp. Date:

MEDI-FLEX

Applicator barrel artwork - Labeling Format (100%) for ChloraPrep® One-Step
Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 10.5-mL Applicator

CREATED 5/01/02 REVISED 6/10/02 REVISED 8/20/02 REVISED 1/30/03
REVISED 2/3/03 (annotations) REVISED 2/11/03 REVISED 2/13/03 REVISED 2/17/03

**ChloraPrep® 10.5-mL Applicator**
2% (w/v) Chlorhexidine gluconate
and 70% (v/v) Isopropyl alcohol
Medi-Flex Hospital Products, Overland Park KS

Lot No. Exp. Date

Title: 9 pt antique olive nord
Formulation: 8 pt antique olive bold

REDUCED 65% TO FIT