ATTACHMENT 2

Copy of RLD label (including Directions for Use)
upon which this petition is based

NDC # 054365-400-01 DIN # 02160757

ChloraPrep®

Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v
Patient Preoperative Skin Preparation • 3.0-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 ■ Flammable, keep away from fire or flame ■ Do not use with electrocautery procedures ■ For external use only

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.
- maximum treatment area for one applicator is approximately 130 cm^2 (approx. 4 x 5 in.). 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 Hospital Products, Inc., Overland Park, KS 66210

Single Use
Applicator is STERILE if package is intact
Catalog No. 260400