

The logo for HIBICLENS, featuring the brand name in a bold, black, sans-serif font with a registered trademark symbol.

HIBICLENS® Antiseptic/Antimicrobial Skin Cleanser
(chlorhexidine gluconate)
<http://www.mountainside-medical.com>



DESCRIPTION

HIBICLENS is an antiseptic antimicrobial skin cleanser possessing bactericidal activities. HIBICLENS contains 4% w/v **HIBITANE®** (chlorhexidine gluconate), a chemically unique hexamethylenebis biguanide with inactive ingredients: Fragrance, isopropyl alcohol 4%, purified water, Red 40, and other ingredients, in a mild, sudsing base adjusted to pH 5.0-6.5 for optimal activity and stability as well as compatibility with the normal pH of the skin.

ACTION

HIBICLENS is bactericidal on contact. It has antiseptic activity and a persistent antimicrobial effect with rapid bactericidal activity against a wide range of microorganisms, including gram-positive bacteria and gram-negative bacteria such as *Pseudomonas aeruginosa*. The effectiveness of HIBICLENS is not significantly reduced by the presence of organic matter, such as blood.¹

In a study² simulating surgical use, the immediate bactericidal effect of HIBICLENS after a single six-minute scrub resulted in a 99.9% reduction in resident bacterial flora, with a reduction of 99.98% after the eleventh scrub. Reductions on surgically gloved hands were maintained over the six-hour test period. HIBICLENS displays persistent antimicrobial action. In one study², 93% of a radiolabeled formulation of HIBICLENS remained present on uncovered skin after five hours. HIBICLENS helps prevent skin infection thereby reducing the risk of cross-infection.

INDICATIONS

HIBICLENS is indicated for use as a surgical scrub, as a health-care personnel handwash, as a patient pre-operative skin preparation, and as a skin wound cleanser and general skin cleaner.

SAFETY

The extensive use of chlorhexidine gluconate for over 20 years outside the United States has produced no evidence of absorption of the compound through intact skin. The potential for producing skin reactions is extremely low. HIBICLENS can be used many times a day without causing irritation, dryness, or discomfort. Experimental studies indicate that when used for cleaning superficial wounds, HIBICLENS will neither cause additional tissue injury nor delay healing.

WARNINGS

FOR EXTERNAL USE ONLY. KEEP OUT OF EYES, EARS AND MOUTH. HIBICLENS SHOULD NOT BE USED AS A PREOPERATIVE SKIN PREPARATION OF THE FACE OR HEAD. MISUSE OF HIBICLENS HAS BEEN REPORTED TO CAUSE SERIOUS AND PERMANENT EYE INJURY WHEN IT HAS BEEN PERMITTED TO ENTER AND REMAIN IN THE EYE DURING SURGICAL PROCEDURES. IF HIBICLENS SHOULD CONTACT THESE AREAS, RINSE OUT PROMPTLY AND THOROUGHLY WITH WATER.

Avoid contact with meninges. HIBICLENS should not be used by persons who have a sensitivity to it or its components. Chlorhexidine gluconate has been reported to cause deafness when instilled in the middle ear through perforated eardrums. Irritation, sensitization, and generalized allergic reactions have been reported with chlorhexidine-containing products, especially in the genital areas. If adverse reactions occur, discontinue use immediately and if severe, contact a physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Accidental ingestion: Chlorhexidine gluconate taken orally is poorly absorbed. Treat with gastric lavage using milk, egg white, gelatin or mild soap. Employ supportive measures as appropriate. Avoid excessive heat (above 104°F).

Wounds which involve more than the superficial layers of the skin should not be routinely treated with HIBICLENS. HIBICLENS should not be used for repeated general skin cleansing of large body areas except in those patients whose underlying condition makes it necessary to reduce the bacterial population of the skin. To use, thoroughly rinse the area to be cleansed with water. Apply the minimum amount of HIBICLENS necessary to cover the skin or wound area and wash gently. Rinse again thoroughly.

Preoperative Skin Preparation

Apply HIBICLENS liberally to surgical site and swab for at least two minutes. Dry with a sterile towel. Repeat procedure for an additional two minutes and dry with a sterile towel.

HEALTH-CARE PERSONNEL USE

Surgical Hand Scrub

Directions for use of HIBICLENS Antiseptic/Antimicrobial Skin Cleanser: Wet hands and forearms with water. Scrub for 3 minutes with about 5 mL of HIBICLENS and a wet brush, paying particular attention to the nails, cuticles, and interdigital spaces. A separate nail cleaner may be used. Rinse thoroughly. Wash for an additional 3 minutes with 5 mL of HIBICLENS and rinse under running water. Dry thoroughly.

Personnel Hand Wash

Wet hands with warm water. (Avoid using very cold or very hot water.) Dispense about 5 mL of HIBICLENS into cupped hands. Wash for 15 seconds. (Do not use excessive pressure to produce additional lather.) Rinse thoroughly with warm water. Dry thoroughly.

IMPORTANT LAUNDERING ADVICE FOR HOSPITAL STAFF AND OTHER USERS OF ANTISEPTIC PATIENT SKIN PREPARATIONS CONTAINING CHLORHEXIDINE GLUCONATE

Chlorhexidine gluconate is a unique agent that closely fits the definition of an ideal antimicrobial agent, having (among others) one of the most important characteristics of persistent activity. This persistence is due to chlorhexidine gluconate binding to the protein of the skin and, thus, being available for residual activity over a relatively long period of time.

Chlorhexidine gluconate, however, binds not only to protein of the skin, but also to many fabrics, particularly cotton. Thus, special laundering procedures should be considered when such products contact these fabrics. As a result of such contact, chlorhexidine gluconate may become adsorbed onto the fabric and not be removed by washing.

If sufficient available chlorine is present during the washing procedure, a fast brown stain may develop due to a chemical reaction between chlorhexidine gluconate and chlorine.

SUGGESTED LAUNDERING PROCEDURES TO LIMIT STAINING

- 1. Not Aging.** Avoid allowing the product to age (set) on unwashed linens.
- 2. Flushing and Washing.** A flush operation as the initial step in the wash process is helpful in the laundering of linen exposed to chlorhexidine gluconate. Such flushing is also important in the laundering of linen which contains organic materials such as blood or pus. For best results, warm water flushes (90°-100°F) are recommended. After a number of initial flushings followed by a washing with a low alkaline/non-chlorine detergent, most articles which come in contact with chlorhexidine gluconate should have an acceptable level of whiteness. If a rewash process using bleach is necessary to achieve a greater degree of whiteness, the bleach used should be non-chlorine bleach.
- 3. Not Using Chlorine Bleach.** Modern laundering methods often make the use of chlorine bleach unnecessary. It is worthwhile trying to wash without chlorine to ascertain if the resulting degree of whiteness is acceptable. Omission of chlorine from the laundering process can extend the useful life of cotton articles since oxidizing bleaches such as chlorine may cause some damage to cellulose even when used in low concentration.
- 4. Changing to a Peroxide-Type Bleach, Such as Sodium Perborate, Sodium Percarbonate or Hydrogen Peroxide.** This should eliminate the reaction that could occur with the use of chlorine bleaches. If a chlorine bleach must be used, a concentration of less than 7 ppm available chlorine (1/10 the normal bleach level) is suggested to minimize possible staining.

A NOTE ON LAUNDERING OF PERSONAL CLOTHING

The laundering procedures set forth above using low alkaline, non-chlorinated laundry detergents are also applicable to laundering of uniforms and lab coats. Commercially available laundry detergents that do not contain chlorine include Borax, Borateem, Dreft, Oxydol, and Ivory Snow. These products, however, will not remove stains previously set into the fabric.

RECLAMATION OF STAINED LINES

For those linens which previously have been stained due to the chemical reaction between chlorhexidine gluconate and chlorine, the following laundering procedure may be helpful in reducing the visible stain:

Operation Water Temperature Time Supplies

Level (Min) 100 lb___
Break Low 180°F 20 1.5 lb oxalic acid
Flush High Cold 1 ___
Emulsify Low 160°F 5 18 oz emulsifier
Flush High Cold 1 ___
Bleach Low 180°F 20 2 lb alkali builder and 1 lb organic bleach
Rinse High Cold 1 ___
Antichlor High Cold 2 4 oz antichlor
Rinse High Cold 1 ___
Rinse High Cold 1 ___
Sour Low Cold 4 2 oz rust removing sour

HOW SUPPLIED

For general hand washing locations: pocket-size, 15 mL foil packettes; plastic disposable bottles of 4 oz and 8 oz with dispenser caps; and 16 oz filled globes. *For surgical scrub areas:* plastic disposable bottles of 32 oz and 1 gal. The 32-oz bottle is designed for a special foot-operated wall dispenser. A hand-operated wall dispenser is available for the 16-oz globe. Hand pumps are available for 16 oz, 32 oz, and 1 gal sizes. Store at controlled room temperature 20-25°C (68-77°F) [see USP].

Liquid: NDC 0234-057504, 0234-057508, 0234-0575 16, 0234-057532, & 0234-05759 1).

REFERENCES

- 1 Lowbury, E.J.L and Lilly, H.A: The effect of blood on disinfection of surgeons' hands, Brit. J. Surg. 61:19-21 (Jan.) 1974
- 2 Peterson AF, Rosenberg A, Alatar SD: Comparative evaluation of surgical scrub preparations, Obstet, 146:63- 65 (Jan.) 1978

Distributed by:

Mountainside Medical
Equipment

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Rev B 10/04