ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate solution
Cardinal Health
----------

Drug Facts

Active Ingredient
Chlorhexidine gluconate 4% Solution

Purpose
Antiseptic

Uses
- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease
- **patient preoperative skin preparation:** for the preparation of the patient's skin prior to surgery
- **skin wound and general skin cleansing**

Warnings

For external use only

Do not use
- if you are allergic to chlorhexidine gluconate or any other ingredients
- in contact with meninges
- in the genital area
- as a preoperative skin preparation of the head or face

When using this product
- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population of skin

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
- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
Surgical hand scrub:
- wet hands and forearms under running water
- scrub for 3 minutes with about 5 mL of product and a wet brush, paying close 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 product and rinse under running water
- dry thoroughly

Healthcare personnel handwash:
- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for about 15 seconds
- rinse and dry thoroughly

Patient preoperative skin preparation:
- apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel
- repeat the procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general skin cleansing:
- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

Other information
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients
cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol.

Questions or comments?
call 1-800-587-3721, Monday through Friday 8:00 AM to 4:30 PM CST

Warning: This product contains a chemical (cocamide DEA) known to the State of California to cause cancer.

Laundring/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products. Rinse completely and use only non-chlorine detergents.

*This product is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiclens®.

Distributed by McKesson
One Post Street, San Francisco, CA 94104
Money Back Guarantee
www.healthmart.com/healthmartbrand
Principal Display
NDC 37205-595-34
Leader®
Compare to Hibiclens® active ingredient*
Antiseptic Skin Cleanser
(CHLORHEXIDINE GLUCONATE 4% SOLUTION)
ANTISEPTIC/ANTIMICROBIAL SKIN CLEANSER
FOR EXTERNAL USE ONLY
DYE FREE
8FL OZ (237mL)
**ANTISEPTIC SKIN CLEANSER**
chlorhexidine gluconate solution

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN PRESCRIPTION DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:37205-595</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>TOPICAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNIER4KO0DY52L)</td>
<td>CHLORHEXIDINE GLUCONATE</td>
<td>4 g in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>COCO DIETHANOLAMIDE (UNII: 92005F972D)</td>
<td></td>
</tr>
<tr>
<td>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)</td>
<td></td>
</tr>
<tr>
<td>ISOPROPYL ALCOHOL (UNII: ND2M416302)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0K00R)</td>
<td></td>
</tr>
<tr>
<td>TRIDECYL ALCOHOL (UNII: 8I9428H868)</td>
<td></td>
</tr>
<tr>
<td>GLUCONOLACTONE (UNII: WQ29KQ9POT)</td>
<td></td>
</tr>
<tr>
<td>PEG-75 LANOLIN (UNII: 09179OX7TB)</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:37205-595-</td>
<td>237 mL in 1 BOTTLE, PLASTIC</td>
<td>Type 0: Not a Combination</td>
<td></td>
</tr>
</tbody>
</table>
### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA019125</td>
<td>01/01/2012</td>
<td></td>
</tr>
</tbody>
</table>

**Labeler** - Cardinal Health (097537435)

**Registrant** - Xttrium Laboratories, Inc. (007470579)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xttrium Laboratories, Inc.</td>
<td></td>
<td>007470579</td>
<td>manufacture(37205-595)</td>
</tr>
</tbody>
</table>

Revised: 1/2016