

**ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate solution**  
**Xttrium Laboratories, Inc.**

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**XTT 8oz Leader 4% CHG**

**Active Ingredient**

Chlorhexidine gluconate 4% Solution

**Purpose**

Antiseptic

**Uses**

- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease
- **skin wound and general skin cleansing**

**Warnings**

**For external use only**

**Allergy alert:**

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

**Do not use**

- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area

**When using this product**

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye 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 advised by a health care provider.

### **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.

### **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

### **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?**

**1-800-587-3721**

**Warning:** This product can expose you to coconut oil diethanolamine condensate (cocamide diethanolamine), which is known to the State of California to cause cancer. For more information fo to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**Laundering/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®.

## Principal Display

LEADER

NDC 70000-0407-1

Antiseptic Skin Cleanser

Chlorhexidine Gluconate 4% Solution

Antiseptic / Antimicrobial Skin Cleanser

For External Use Only

COMPARE TO HIBICLENS® active ingredient\*

100% Money Back Guarantee

8 fl oz (237 mL)

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**LEADER**  
NDC 70000-0407-1  
**Antiseptic Skin Cleanser**  
Chlorhexidine Gluconate 4% Solution  
Antiseptic / Antimicrobial Skin Cleanser

Great For Hand Hygiene  
For Skin Wound and General Skin Cleansing

COMPARE TO HIBICLENS® active ingredient\*

8 FL OZ (237 mL)

FOR EXTERNAL USE ONLY

TAMPERING EVIDENT:  
DO NOT USE IF shrink seal neckband is broken or missing  
CIN 5454889 REV. 8/23

0 96295 13506 0

<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose</b> Chlorhexidine gluconate 4% solution ..... Antiseptic</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>healthcare personnel handwash: helps reduce bacteria that potentially can cause disease</li> <li>skin wound and general skin cleansing</li> </ul> <p><b>Warnings</b> For external use only</p> <p><b>Allergy alert:</b> This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> <li>wheezing/difficulty breathing</li> <li>shock</li> <li>hives</li> <li>facial swelling</li> <li>rash</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product</li> <li>in contact with meninges</li> <li>in the genital area</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>keep out of eyes, ears and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.</li> <li>if solution should contact these areas, rinse out promptly and thoroughly with water</li> <li>wounds which involve more than the superficial layers of the skin should not be routinely treated</li> <li>repeated general skin cleansing of large body areas should not be done except when advised by a health care provider</li> </ul> <p><b>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs.</b> These may be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Healthcare personnel handwash:</b></p> <ul style="list-style-type: none"> <li>wet hands with water</li> <li>dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds</li> <li>rinse and dry thoroughly</li> </ul> <p><b>Skin wound and general skin cleaning:</b></p> <ul style="list-style-type: none"> <li>thoroughly rinse the area to be cleaned with water</li> <li>apply the minimum amount of product necessary to cover the skin or wound area and wash gently</li> <li>rinse again thoroughly</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 20-25°C (68-77°F)</li> <li>avoid excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive ingredients</b> cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol</p> <p><b>Questions?</b> 1-800-587-3721</p> <p>DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017 www.myleader.com 1-800-200-6313</p>
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Lamination/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach.

WARNING: Cancer - www.P65Warnings.ca.gov

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## ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0116-0407
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZ N16)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>COCO DIETHANOLAMIDE</b> (UNII: 92005F972D)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TRIDECYL ALCOHOL</b> (UNII: 8I9428H868)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>PEG-75 LANOLIN</b> (UNII: 09179OX7TB)	
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0407-01	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2012	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	01/01/2012	

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

Revised: 4/2025

Xttrium Laboratories, Inc.