

**ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid**  
**Chain Drug Marketing Association Inc.**

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**Quality Choice Drug Facts**

**Active Ingredients**

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

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control center right away

**Stop use and ask doctor if**

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

## **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

## **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 5ml of product into cupped hands and wash in a vigorous manner for about 15 seconds
- rinse and dry thoroughly

## **Skin wound and normal 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

## **Other Information**

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING

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

**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®.

**Warning:** Cancer - [www.P65Warnings.gov](http://www.P65Warnings.gov)

**Laundering/Cleaning Instructions:** Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach.

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

## Package label and principal display panel

Quality Choice

NDC 63868-940-08

Compare to the active ingredient in HIBICLENS®\*

Antiseptic Skin Cleanser

Antiseptic/Antimicrobial Skin Cleanser

Chlorhexidine Gluconate 4% Solution

Reduces Bacteria on the Skin

Net Contents: 8FL OZ (237 mL) BOTTLE

FOR EXTERNAL USE ONLY

DYE FREE

1061QC08LBLG

The image shows a detailed product label for 'Antiseptic Skin Cleanser'. The label is divided into several sections: a top header with the 'QC QUALITY CHOICE' logo and NDC number; a main title section with 'Antiseptic Skin Cleanser' and 'Antiseptic/Antimicrobial Skin Cleanser'; a description section listing 'Chlorhexidine Gluconate 4% Solution' and 'Reduces Bacteria on the Skin'; a barcode with the number 6 35515 96757 1; and a large 'Drug Facts' section. The 'Drug Facts' section is organized into columns and includes information on active ingredients, uses, warnings, directions, and other information. A vertical warning label on the right side of the 'Drug Facts' section reads: 'Laundering/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. WARNING: Cancer - www.P65Warnings.gov'. At the bottom right, there is a 'SAFETY' logo and distribution information for CDMA, Inc.

**QC QUALITY CHOICE**  
NDC 63868-940-08  
Compare to the active ingredient in HIBICLENS®\*

# Antiseptic Skin Cleanser

Antiseptic/Antimicrobial Skin Cleanser

Chlorhexidine Gluconate 4% Solution  
Reduces Bacteria on the Skin  
FOR EXTERNAL USE ONLY  
DYE FREE

6 35515 96757 1  
DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING  
8 fl oz (237 mL) BOTTLE

Drug Facts		Drug Facts (continued)		Drug Facts (continued)	
<b>Active ingredient</b> Chlorhexidine gluconate 4% solution	<b>Purpose</b> Antiseptic	<b>When using this product</b> <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>	<b>Healthcare personnel handwash:</b> <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>	<b>Skin wound and general skin cleaning:</b> <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>	<b>Other information</b> <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>
<b>Uses</b> <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>	<b>Warnings</b> For external use only <b>Allergy alert:</b> This product may cause a severe allergic reaction. Symptoms may include: <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> If an allergic reaction occurs, stop use and seek medical help right away.	<b>Stop use and ask a doctor</b> if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.	<b>Inactive ingredients</b> cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol	<b>Questions?</b> 1-800-587-3721	<b>*This product is not manufactured or distributed by Regent Medical Limited (United Kingdom Corp.), owner of the registered trademark Hibiclens®.</b>
<b>Do not use</b> <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 meningitis</li><li>in the genital area</li></ul>	<b>Directions</b> <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>				

Distributed by CDMA, Inc.  
Novi, MI 48075  
[www.qualitychoice.com](http://www.qualitychoice.com)  
Questions: 800-935-2362  
1061QC08LBLG

## ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-940
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	
<b>COCO DIETHANOLAMIDE</b> (UNII: 92005F972D)	
<b>PEG-75 LANOLIN</b> (UNII: 09179OX7TB)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TRIDECYL ALCOHOL</b> (UNII: 8I9428H868)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63868-940-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2014	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA019125	05/01/2014	

**Labeler** - Chain Drug Marketing Association Inc. (011920774)

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

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Xttrium Laboratories, Inc.		007470579	manufacture(63868-940)