

## **ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid**

**Topco Associates LLC**

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### **TopCare**

#### **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
- **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 a 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.

### **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

### **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 of comments?**

call **1-800-587-3721** Monday through Friday 8:00 AM to 4:30 PM CST

**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 go to [www.P65Warnings.gov](http://www.P65Warnings.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®.

### **Package label and principal display panel**

NDC 36800-401-50

TopCare® health™

COMPARE TO HIBICLENS® ACTIVE INGREDIENT\*

DYE FREE

Antiseptic Skin Cleanser

(CHLORHEXIDINE GLUCONATE 4% SOLUTION)

ANTISEPTIC / ANTIMICROBIAL SKIN CLEANSER

FOR EXTERNAL USE ONLY

8 FL OZ (237 mL)

NDC 36800-401-50

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**Lift Here**

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<http://topbrnds.com/48zrq1>

✓QUALITY GUARANTEED

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**Drug Facts**

Active ingredient	Purpose
Chlorhexidine gluconate 4% solution	Antiseptic

**Uses**

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## **Drug Facts** (continued)

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**ANTISEPTIC SKIN CLEANSER**

chlorhexidine gluconate 4% liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-401
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:36800-401-50	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2013	
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	11/01/2013	

**Labeler** - Topco Associates LLC (006935977)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(36800-401)

Revised: 6/2019

Topco Associates LLC