

**ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid**  
**Chain Drug Consortium, LLC**

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**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 cleaning**

**Warnings**

**For external use only**

**Allergy alert:** This product may cause 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 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

## **Warning**

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

## **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 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 of comments?**

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

## **Other Safety Information**

### **4PV16BTLLBL**

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Distributed By:

Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

Wayne, PA 19087

MADE IN USA

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

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## **Purpose**

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**Questions or comments?**

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

Premier Value

COMPARE TO THE ACTIVE INGREDIENT IN HIBICLENS®

Antiseptic Skin Cleanser

Antiseptic/Antimicrobial Skin Cleanser

(Chlorhexidine Gluconate 4% solution)

FOR EXTERNAL USE ONLY

DYE FREE

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING

8FL OZ. (237 mL)



COMPARE TO THE ACTIVE INGREDIENT IN HIBICLENS®\*

# Antiseptic Skin Cleanser

ANTISEPTIC/ANTIMICROBIAL SKIN CLEANSER  
(Chlorhexidine Gluconate 4% Solution)

FOR EXTERNAL USE ONLY  
DYE FREE

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING

8 fl oz (237 mL)



▲ Lift Here

4P108BTLBLE



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## Drug Facts

<b>Active ingredient</b>	<b>Purpose</b>
Chlorhexidine gluconate 4% solution	Antiseptic

### Uses

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

## Drug Facts (continued)

### Warnings

For external use only

**Allergy alert:** This product may cause a severe allergic reaction.

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**Drug Facts (continued)**

- wounds which involve more than the superficial layers of the skin should not be routinely treated
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**Drug Facts (continued)**

- rinse again thoroughly

**Other information**

- store at 20-25°C (68-77°F)
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**Inactive ingredients** cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

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**Princical Display Panel**

Premier Value

COMPARE TO THE ACTIVE INGREDIENT IN HIBICLENS ®\*

Antiseptic Skin Cleanser

ANTISEPTIC/ANTIMICROBIAL SKIN CLEANSER

(Chlorhexidine Gluconate 4% Solution)

FOR EXTERNAL USE ONLY

DYE FREE

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING

16 fl oz (473 mL)

Premier Value

COMPARE TO THE  
LATEST EQUIVARIANT  
IN THE CLASS

# Antiseptic Skin Cleanser

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4PV16BTLLBL



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Chlorhexidine gluconate 4% solution	Antiseptic

- Uses**
- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
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Lift Here

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### Drug Facts (continued)

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## ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68016-228

Route of Administration 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: 059QF0K00R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-228-00	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	
2	NDC:68016-228-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	10/30/2012	

**Labeler** - Chain Drug Consortium, LLC (101668460)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(68016-228)