# ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid Xttrium Laboratories, Inc.

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## Meijer 4% CHG

# **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

# 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 of may cause deafness when instilled in the middle ear through perforated eatdrums.
- 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.

#### **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 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?**

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

### Other safety information

**Warning:** This product can expose you to cocnut 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.

**Laundering/Cleaning Instructions:** Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and ue only non-chlorine detergents.

DIST. BY MEIJER DISTRIBUTION, INC.

# GRAND RAPIDS, MI 49544

www.meijer.com

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

# Package label and principal display panel

meijer

NDC 41250-162-08

Compare to Hibiclens® active ingredient

antiseptic skin cleanser

(Chlorhexidine Gluconate 4% Solution)

Antiseptic/Antimicrobial Skin Cleanser

REDUCES BACTERIA ON THE SKIN

DYE FREE

FOR EXTERNAL USE ONLY

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING

8 fl oz (237 mL)



Lift Here

\*This product is not manufactured or distributed by Regent Medical Limited, owner of the registered trademark Hibiclens®.



DIST, BY MEUER DISTRIBUTION, INC. GRAND RAPIDS, MI 49544 www.meijer.com

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# Drug Facts

Active ingredient Chlorhexkline gluconate 4% solution

Purpose Antiseptic

- 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

#### Drug Facts (continued)

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- 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.

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  dry thoroughly

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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.

# ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-0162	
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		
LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)			
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: 819428H868)			
GLUCONOLACTONE (UNII: WQ29KQ9POT)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0162- 08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 14	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA0 19 125	0 1/0 1/20 14	

# Labeler - Xttrium Laboratories, Inc. (007470579)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0162)	

Revised: 10/2020 Xttrium Laboratories, Inc.