

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

Premier Value 4% CHG

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 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 healthcare 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 contains a chemical known to the State of California to cause cancer.

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.

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

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

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

8 fl oz (237 mL)



▶ Lift Here

4P10&TLLE



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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.

Drug Facts

Active ingredient	Purpose
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

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

Symptoms may include:

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Do not use

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- 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.
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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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Skin wound and general skin cleansing:

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Drug Facts (continued)

- rinse again thoroughly

Other information

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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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Laundry/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.

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Premier Value

COMPARE TO THE ACTIVE INGREDIENT IN HIBICLENS®

Antiseptic Skin Cleanser

ANTISEPTIC/ANTIMICROBIAL SKIN CLEANSER

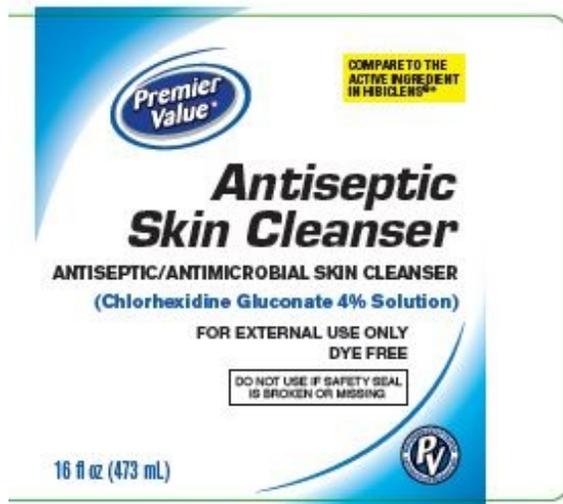
(Chlorhexidine Gluconate 4% Solution)

FOR EXTERNAL USE ONLY

DYE FREE

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING

16 fl oz (473 mL)



4PV16BTLLBL



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Drug Facts (continued)

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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:0116-0228
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 mg in 100 mL
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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: 819428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0228-00	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/30/2012	
2	NDC:0116-0228-16	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 - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0228)

Revised: 10/2020

Xttrium Laboratories, Inc.