

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

Walgreens 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
- 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 a 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 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?

call **1-800-925-4733**

Laundering/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine-releasing products. Rinse completely and use only non-chlorine detergents.

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

‡Walgreens Pharmacist Survey Study, November 2014

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

Distributed by: Walgreen Co.

200 Wilmot RD., Deerfield, IL 60015

100% Satisfaction Guaranteed

walgreens.com

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Package label and principal display panel

Walgreens

Compare to the Hibiclens® active ingredient

NDC 0363-1061-08

Dye-Free

Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION / ANTISEPTIC / ANTIMICROBIAL SKIN CLEANSER

DYE FREE

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

8 FL OZ (237 mL)



Walgreens Pharmacist Recommended
Walgreens Pharmacist Survey

[†]This product is not manufactured or distributed by Mölnlycke
Healthcare, owner of the registered trademark Hibiclens®.

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4WA08BTLLBLF

ITEM 454559 W10071-1018-L

3 11917 12239 7

Drug Facts

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**

▲ Lift Here

Drug Facts (continued)

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 health care provider

Stop use and ask a 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
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- 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
- 

Drug Facts (continued)
Skin wound and general skin cleansing: <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 1-800-925-4733

W1061

ORG0918-F
REV-1018

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.

VALUE SIZE

NDC 0363-1061-16

Walgreens

Compare to Hibiclens® active ingredient

Dye-Free Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION / ANTISEPTIC / ANTIMICROBIAL SKIN CLEANSER

DYE FREE

Skin wound & general skin cleansing

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

16 FL OZ (473 mL)

VALUE SIZE

NDC 0363-1061-16

Walgreens

Compare to Hibiclens® active ingredient^{††}

Dye-Free Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4%
SOLUTION / ANTISEPTIC / ANTIMICROBIAL SKIN CLEANSER

DYE FREE

- Skin wound & general skin cleansing

16 FL OZ (473 mL)

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

Walgreens Pharmacist Recommended
Walgreens Pharmacist Survey
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owner of the registered trademark Hibiclens®.



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Walgreens Pharmacist Recommended
Walgreens Pharmacist Survey

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4WA16BTLLBLC

REV0718-RF

Drug Facts

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

▲ Lift Here

Drug Facts (continued)

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Drug Facts (continued)

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Inactive ingredients

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Questions or comments? call 1-800-925-4733

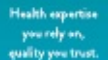
Laundry/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

Carton

NDC 0363-1061-15

Walgreens, Co.

0.5 FL OZ (15 mL)



Walgreens

NDC 33304-014-01

Compare to Hibiclens® active ingredient†

Antiseptic Skin Cleanser Kit

CHLORHEXIDINE GLUCONATE
4% SOLUTION / ANTISEPTIC /
NON-STERILE SOLUTION
ANTIMICROBIAL SKIN CLEANSER

DYE FREE

ALL-IN-ONE KIT

PRE-SURGICAL

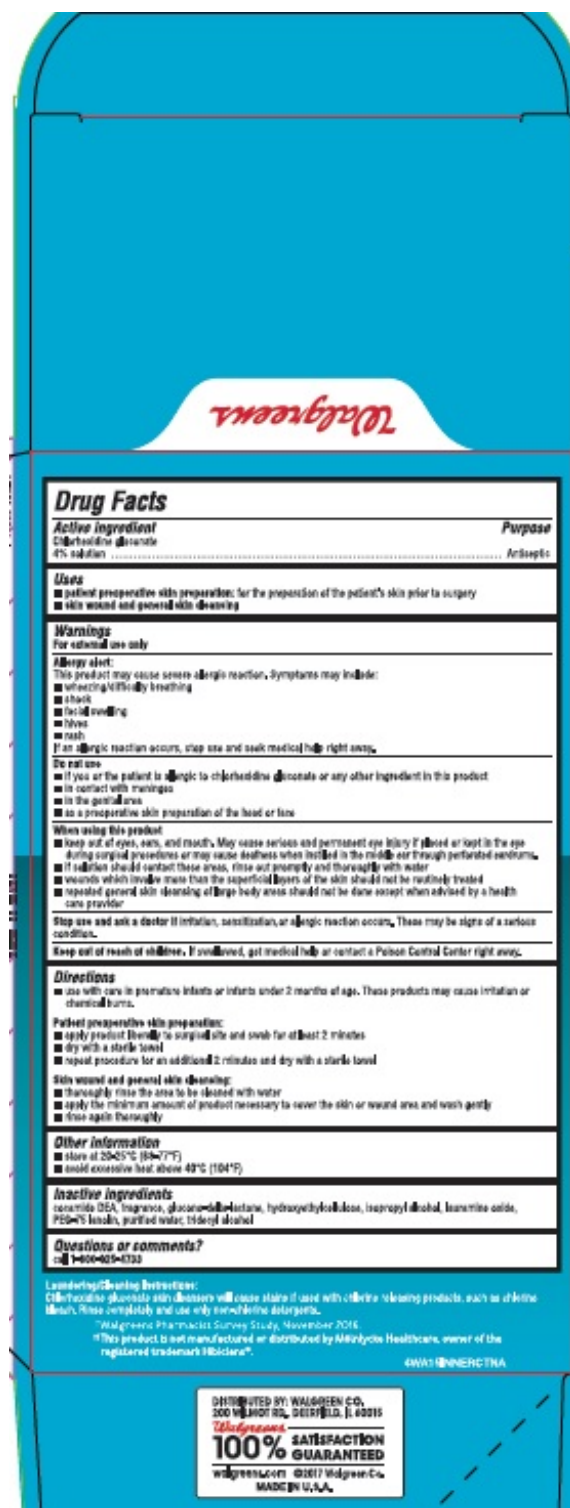
- Patient pre-operative skin preparation
- Wound & general skin cleansing
- Single-Use

2

KITS
1 SPONGE & 1 (15 ML)
LIQUID POUCH EACH

BEFORE USING THIS PRODUCT, CAREFULLY READ ALL WARNINGS AND
FOLLOW THE DIRECTIONS IN THE DRUG FACTS AND PACKAGE INSERT

NET WT 0.17 LB (79.62 g)



Lidstock

NDC 0363-1061-15

Walgreens, Co.

Chlorhexidine Gluconate 4% Solution

Antiseptic Skin Cleansing Kit

Distributed by:

Xtrium Laboratories, Inc.,

Mount Prospect, IL 60056

4WAL15LIDSTOCKA

0.5 FL OZ (15 mL)



Packet

NDC 0363-1061-15

Walgreens, Co.

Chlorhexidine Gluconate 4% Solution

Antiseptic Skin Cleansing Convenience Kit

Distributed by:

Xttrium Laboratories, Inc.,

Mount Prospect, IL 60056

4WAL15PACKETA

0.5 FL OZ (15 mL)





ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4 % liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0 116-0 16 1
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8 E) (CHLORHEXIDINE - UNII:R4KO0DY52L)		CHLORHEXIDINE GLUCONATE	4 mg in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
LAURAMINE O XIDE (UNII: 4F6FC4MI8 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: 8I9428H868)				
GLUCONOLACTONE (UNII: WQ29KQ9POT)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0161-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2011	
2	NDC:0116-0161-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2011	
3	NDC:0116-0161-15	15 mL in 1 KIT; Type 1: Convenience Kit of Co-Package	01/01/2017	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA019125	05/01/2011	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0161)

Revised: 10/2020

Xttrium Laboratories, Inc.