

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

XTT Rite Aid 4% CHG 8oz/16oz

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 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 eardurms.
- 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.

Healthcare personnel handwash:

- wet hands with water
- dispense about 5mL 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?

1-800-587-3721

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

Compare to the active ingredient in **Hibiclens®**

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE 4% SOLUTION

dye free

for external use only

TAMPER-EVIDENT:

DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

8 FL OZ (237 mL)

4RA08BTLLBLJ

Compare to the active ingredient in Hibiclens®

NDC 11822-3678-8

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE 4% SOLUTION

dye free
for external use only

8 FL. OZ. (237 mL)

*THIS PRODUCT IS NOT MANUFACTURED OR DISTRIBUTED BY MÖLNLYCKE HEALTHCARE, OWNER OF THE REGISTERED TRADEMARK HIBICLENS®. TAMPER-EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

Drug Facts		Drug Facts (continued)	Drug Facts (continued)
Active ingredient Chlorhexidine gluconate 4% solution	Purpose Antiseptic	When using this product <ul style="list-style-type: none">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 waterwounds which involve more than the superficial layers of the skin should not be routinely treatedrepeated general skin cleansing of large body areas should not be done except when advised by a health care provider	Healthcare personnel handwash: <ul style="list-style-type: none">wet hands with waterdispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 secondsrinse and dry thoroughly Skin wound and general skin cleaning: <ul style="list-style-type: none">thoroughly rinse the area to be cleaned with waterapply the minimum amount of product necessary to cover the skin or wound area and wash gentlyrinse again thoroughly
Uses <ul style="list-style-type: none">healthcare personnel handwash: helps reduce bacteria that potentially can cause diseaseskin wound and general skin cleansing	Warnings For external use only Allergy alert: This product may cause a severe allergic reaction. Symptoms may include: <ul style="list-style-type: none">wheezing/difficulty breathingshockhivesfacial swellingrash If an allergic reaction occurs, stop use and seek medical help right away.	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.	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
Do not use <ul style="list-style-type: none">if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this productin contact with meningesin the genital area		Directions <ul style="list-style-type: none">use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.	Questions? 1-800-587-3721 DISTRIBUTED BY: RITE AID, 200 NELLBERRY COMMONS, ETTERS, PA 17319 www.riteaid.com

Laundry/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. **WARNING: CANCER - WWW.P69/ARINGS.CA.GOV**

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Compare to the active ingredient in **Hibiclens®**

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE 4% SOLUTION

dye free

for external use only

TAMPER-EVIDENT:

DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

16 FL OZ (473 mL)

4RA16BTLLBLC

Compare to the active ingredient in Hibiclens®*

NDC 11822-3678-7

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE 4% SOLUTION
dye free
for external use only

16 FL. OZ. (473 mL)

*THIS PRODUCT IS NOT MANUFACTURED OR DISTRIBUTED BY HILLIARY HEALTH CARE, OWNER OF THE REGISTERED TRADEMARK HIBICLENS®. TAMPER EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

<p>Drug Facts</p> <p>Active ingredient Purpose Chlorhexidine gluconate 4% solution Antiseptic</p> <p>Uses</p> <ul style="list-style-type: none"> ■ healthcare personnel handwash: helps reduce bacteria that potentially can cause disease ■ skin wound and general skin cleansing <p>Warnings For external use only</p> <p>Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> ■ wheezing/difficulty breathing ■ shock ■ hives ■ facial swelling ■ rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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 	<p>Drug Facts (continued)</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ 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 <p>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
<p>Drug Facts (continued)</p> <p>Healthcare personnel handwash:</p> <ul style="list-style-type: none"> ■ wet hands with water ■ dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds ■ rinse and dry thoroughly <p>Skin wound and general skin cleaning:</p> <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 <p>Other information</p> <ul style="list-style-type: none"> ■ store at 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F) <p>Inactive ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol</p> <p>Questions? 1-800-587-3721</p> <p style="font-size: 8px;">DISTRIBUTED BY: RITE AID, 200 NEWBERRY COMMONS, ETTER, PA 17319 www.riteaid.com</p>	<p style="font-size: 8px;">Laundry/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach.</p> <p style="font-size: 8px;">WARNING: CANCER - WWW.P501WARNINGS.CA.GOV</p> <p style="font-size: 8px;">4RA16BTLLBLC</p> <p style="font-size: 8px;">11822-3678-7 5</p> <p style="font-size: 8px;">0</p>

ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-3678
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 OXIDE (UNII: 4F6FC4MI8W)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)	
ISOPROPYL ALCOHOL (UNII: ND2M41630Z)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-3678-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2013	
2	NDC:0116-3678-07	473 mL in 1 BOTTLE; 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	01/01/2013	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-3678)

Revised: 12/2023

Xttrium Laboratories, Inc.