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

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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 ${}^{l\!R}$.

Package label and principal display panel

Compare to the active ingredient in Hibiclens®

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE 4% SOLUTION

dye free

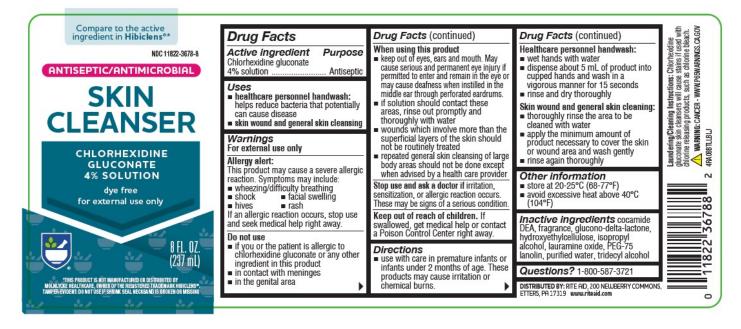
for external use only

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**®

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE 4% SOLUTION

dye free

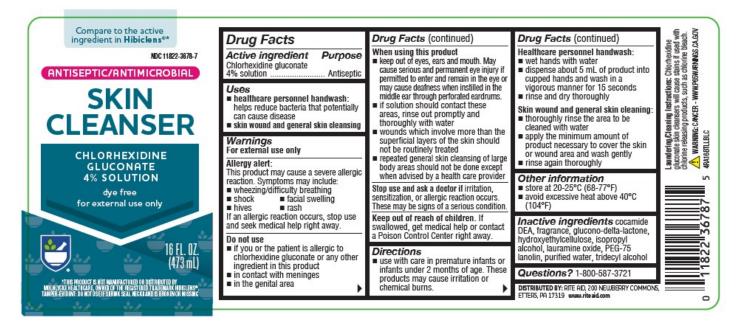
for external use only

TAMPER-EVIDENT:

DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

16 FL OZ (473 mL)

4RA16BTLLBLC



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								
Ingree	Ingredient Name		Basis of Strength		Strength				
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4K00DY52L)			CHLORHEXIDINE GLUCONATE		4 mg in 100 mL				
Inactive Ingredients									
Ingredient Name					Strength				
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)									
COCO DIETHANOLAMIDE (UNII: 9	2005F972D)								
PEG-75 LANOLIN (UNII: 091790X7	TB)								
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)									
ISOPROPYL ALCOHOL (UNII: ND2M416302)									
WATER (UNII: 059QF0KO0R)									
TRIDECYL ALCOHOL (UNII: 819428H868)									
GLUCONOLACTONE (UNII: WQ29KQ9POT)									

Packaging								
#	ltem 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					
	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				
ND	A	NDA019125	01/01/2013					
ND								

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.