ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid Rite Aid

4% Daylogic 8oz

Active Ingredient

Chlorhexidine Gluconate 4% Solution

Purpose

Antiseptic

Uses

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms proir to surgery or patient care
- **healthcare personnel handwash:** helkps 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:

- wheexing/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 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 healthcare provider

Stop use and ask a doctor if

irritationm 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 with 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 seperate 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 general skin cleansing:

- thoroughly rinse the area to be cleaned with water
- apply this 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

Laundering/Cleaning Instrucitons: 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.

NDC 11822-0116-5

daylogic

ADVANCED

ANTIMICROBIAL

handwash

4% CHLORHEXIDINE GLUCONATE

Antiseptic Solution

Clinically Proven to Reduce Bacteria on the Skin

FDA Approved Formula

Used by Healthcare Professionals

NO PHTHALATES

NO TRICLOSAN

DYE FREE

4DAY08BTLLBL

8 FL OZ (237 mL)



Drug Facts (continued)

- 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 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.

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 with 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 general 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

Drug Facts (continued)

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

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.

ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0116	
Route of Administration	TOPICAL			

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
	CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII: R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 g in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
COCO DIETHANOLAMIDE (UNII: 92005F972D)			
PEG-75 LANOLIN (UNII: 091790X7TB)			
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)			
WATER (UNII: 059QF0KO0R)			
GLUCONOLACTONE (UNII: WQ29KQ9POT)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
TRIDECYL ALCOHOL (UNII: 819428H868)			

ı	Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date		
	1 NDC:11822- 0116-5	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2021		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	03/25/2021	

Labeler - Rite Aid (014578892)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment				
Name	Address	ID/FEI	Business Operations	
Xttrium Laboratories, Inc		007470579	manufacture(11822-0116)	

Revised: 3/2021 Rite Aid