

CLINICLEAN- chlorhexidine gluconate 4% solution
Xttrium Laboratories, Inc.

4% HR Pharma 4-oz Foamer

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
- 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 the 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 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 with water
- scrub for 3 minutes with 4 full pumps (6 grams) 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 4 full pumps (6 grams) of product and rinse under running water
- dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense 4 full pumps (6 grams) of product into cupped hands and wash in a vigorous manner for 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

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

Laudering/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.

Package Label

NDC 69464-901-05

REF 90604

CliniClean

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution with Foaming Pump

Surgical Hand Scrub, Heath Personnel Hand Wash, General Skin & Wound Cleanser

Net Content: 4fl oz (118 mL)

DYE FREE

Manufactured for:

HR Pharmaceuticals, Inc.

York, PA 17402

clinclean.com

Rev 4176 Rev 2

(12/2023)

4HRP04FMBTLLBLA

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Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution
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HR Pharmaceuticals, Inc. 4176 Rev 2
York, PA 17402 | cliniclean.com (10/2023)

Drug Facts

Active ingredient Purpose
Chlorhexidine gluconate 4% solution ... Antiseptic

Uses

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
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- **skin wound and general skin cleansing**

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Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

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CLINICLEAN

chlorhexidine gluconate 4% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-0901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0901-05	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	03/15/2023	

Labeler - Xttrium Laboratories, Inc. (007470579)**Registrant** - Xttrium Laboratories, Inc. (007470579)**Establishment**

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc		007470579	manufacture(0116-0901)

Revised: 12/2023

Xttrium Laboratories, Inc.