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

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### XTT 4% HR Pharma 8oz, 16oz, & 32oz

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 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
- wound 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.

#### Direction

• 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 throughly
- 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

#### 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

# Laundry/Cleaning Instrucations

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.

### **Packaging**

NDC 69464-901-08

**REF 90208** 

CliniClean

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

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

Net Contents: 8 fl oz (237 mL)

DYE FREE

Manufactured for:

HR Pharmaceutials, Inc.

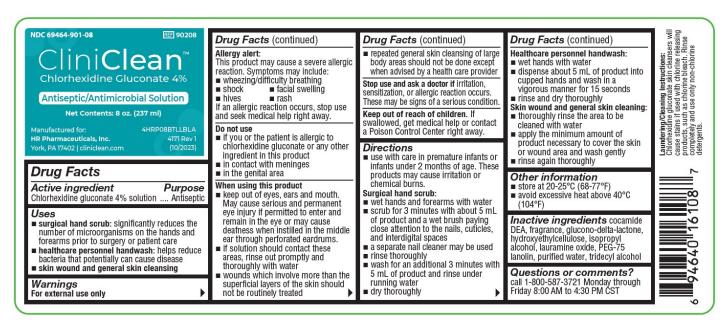
York, PA 17402

cliniclean.com

4171 Rev 1

(10/2023)

4HRP08BTLLBLA



#### CliniClean

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

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

Net Contents: 16 fl oz (473 mL)

DYE FREE

Manufactured for:

HR Pharmaceutials, Inc.

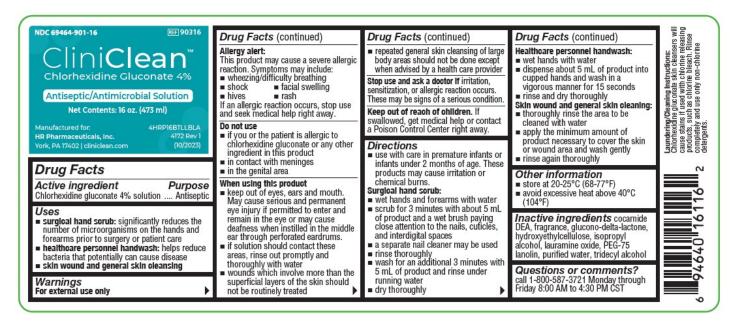
York, PA 17402

cliniclean.com

4172 Rev 1

(10/2023)

4HRP16BTLLBLA



NDC 69464-901-32

REF 90432

CliniClean

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

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

Net Contents: 32 fl oz (946 mL)

DYE FREE

Manufactured for:

HR Pharmaceutials, Inc.

York. PA 17402

cliniclean.com

Rev 4171-0 (02/2023)

4HRP32BTLLBL



#### Drug Facts Drug Facts (continued) Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away Active ingredient Purpose Directions 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 ■ use with care in premature infants or infants under 2 months of age. These products use with care in premature infants or infants under 2 months of age. I nese prouucis may cause irritation or chemical burns. Surgical hand scrub: we thands 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 inse thoroughly wash for an additional 3 minutes with 5 mL of product and rinse under running water downthroughly disease skin wound and general skin cleansing Warnings For external use only wash for an adunional a minutes with 6 mL or product and ninse under running wan dry throughly Healthcare personnel handwash: wet hands with water dispense about 5 mL of product into cupped hands and wash in a vigorous manner Allergy alert: This product may cause a severe allergic reaction. Symptoms may include: wheezing/difficulty breathing I dispense about 5 mil. of product into cupped hands and wash in a vigorous manner for 15 seconds rince 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 an wash gently rinse again thoroughly shock facial swelling Tacks swemmy hives rash if an allergic reaction occurs, stop use and seek medical help right away. Do not use ■ if you or the patient are allergic to chlorhexidine gluconate or any other ingredient in this product in contact with meninges Other information in the genital area ■ store at 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F) In the gential 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 Inactive ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified wat Questions or comments? rounnely treated repeated general skin cleansing of large body areas should not be done except when advised by a health care provider 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.

#### **CLINICLEAN**

chlorhexidine gluconate 4% solution

# **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:0116-0901

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

**Route of Administration TOPICAL** 

# **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE -**CHLORHEXIDINE** 4 q UNII:R4KO0DY52L) **GLUCONATE** in 100 mL

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0116-0901- 08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023		
2	NDC:0116-0901- 16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023		
3	NDC:0116-0901- 32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NDA	NDA019125	03/23/2023			

# **Labeler -** Xttrium Laboratories, Inc. (007470579)

# **Registrant -** Xttrium Laboratories, Inc. (007470579)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0901)		

Revised: 12/2023 Xttrium Laboratories, Inc.