

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

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**4% HR Pharma 15 mL Packets, 15mL Carton, 4oz Flip Top**

**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
- **patient preoperative skin preparation:** for the preparation of the patient's skin prior to surgery
- **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 placed or kept in the eye during surgical procedures 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 about 5mL 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 5mL of product and rinse under running water
- dry thoroughly

### **Healthcare personnel handwash:**

- wet hands with water
- dispense about 5mL of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

### **Patient preoperative skin preparation:**

- apply product liberally to surgical site and swab for at least 2 minutes
- dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

### **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.

## **Display Panels**

NDC 69494-901-04

REF 90104

CliniClean

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

Non-Sterile

Patient Pre-Operative Prep, Surgical Hand Scrub, Healthcare Personnel Hand Wash.  
General Skin & Wound Cleanser

For Single-Use

Net Content: 4 fl oz (118mL)

DYE FREE

Manufactured for:

HR Pharmaceuticals, Inc.

York, PA 17402

[clinclean.com](http://clinclean.com)

Rev 4170-0 (02/2023)

4HRP04BTLLBL

NDC 69464-901-04 REF 90104

# CliniClean™

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

**Non-Sterile**

Patient Pre-Operative Prep, Surgical Hand Scrub,  
Healthcare Personnel Hand Wash,  
General Skin & Wound Cleanser  
For Single-Use

Net Contents: 4 fl oz (118 mL)

**DYE FREE**



Manufactured for:  
HR Pharmaceuticals, Inc.  
York, PA 17402  
cliniclean.com  
Rev 4170-0 (02/2023)  
4HRP04BTLLBL

NDC 69464-901-04 REF 90104

# CliniClean™

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

**Non-Sterile**

Patient Pre-Operative Prep, Surgical Hand Scrub,  
Healthcare Personnel Hand Wash,  
General Skin & Wound Cleanser  
For Single-Use

Net Contents: 4 fl oz (118 mL)

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Rev 4170-0 (02/2023)  
4HRP04BTLLBL

**Lift Here**

<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Chlorhexidine gluconate 4% solution</p> <p><b>Purpose</b> Antiseptic</p> <p><b>Uses</b> reduces the number of microorganisms on the hands and forearms prior to surgery or patient care heal healthcare personnel hand wash: helps reduce bacteria that potentially can cause disease patient preoperative skin preparation: for the preparation of the patient's skin prior to surgery skin wound and general skin cleansing</p>	<p><b>Questions or comments?</b> Monday through Friday 8:00 AM to 4:30 PM CST call 1-800-587-3721</p>
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<p><b>Drug Facts (continued)</b></p> <p><b>Skin wound and general skin cleansing:</b></p> <ul style="list-style-type: none"> <li>thoroughly rinse the area to be cleaned with water</li> <li>apply the minimum amount of product necessary to cover the skin or wound area and wash gently</li> <li>rinse again thoroughly</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 20-25°C (68-77°F)</li> <li>avoid excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive ingredients</b> cocamide DEA, fragrance, gucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tidecyl alcohol</p> <p><b>Questions or comments?</b> Monday through Friday 8:00 AM to 4:30 PM CST call 1-800-587-3721</p> <p><b>Laundry/Cleaning instructions:</b> 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.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b> For external use only</p> <p><b>Allergy alert:</b> This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> <li>wheezing/difficulty breathing</li> <li>snock</li> <li>facial swelling</li> <li>hives</li> <li>rash</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product</li> <li>in contact with meningitis</li> <li>in the genital area</li> <li>as a preoperative skin preparation of the head or face</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>keep out of the eyes, ears and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when instilled in the middle ear through perforated eardrums.</li> <li>if solution should contact these areas, rinse out promptly and thoroughly with water</li> <li>wounds which involve more than the superficial layers of the skin should not be routinely treated</li> <li>repeated general skin cleansing of large body areas should not be done except when advised by a health care provider</li> </ul> <p><b>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs.</b> These may be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li> </ul> <p><b>Surgical hand scrub:</b></p> <ul style="list-style-type: none"> <li>wet hands and forearms with water</li> <li>scrub for 3 minutes with about 5 mL of product and a wet brush paying close attention to the nails, cuticles, and interdigital spaces</li> <li>a separate nail cleaner may be used</li> <li>rinse thoroughly</li> <li>wash for an additional 3 minutes with 5 mL of product and rinse under running water</li> <li>dry thoroughly</li> </ul> <p><b>Healthcare personnel handwash:</b></p> <ul style="list-style-type: none"> <li>wet hands with water</li> <li>dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds</li> <li>rinse and dry thoroughly</li> </ul> <p><b>Patient preoperative skin preparation:</b></p> <ul style="list-style-type: none"> <li>apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel</li> <li>repeat procedure for an additional 2 minutes and dry with a sterile towel</li> </ul>
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NDC 69494-901-15

REF 901515

Cliniclean

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

Non-Sterile

Patient Pre-Operative Prep, Surgical Hand Scrub, Healthcare Personnel Hand Wash.  
General Skin & Wound Cleanser

For Single-Use

Net Contents: 50 Single-Use 0.5 fl oz (15 mL) Packettes

DYE FREE

Manufactured for:

HR Pharmaceuticals, Inc.

York, PA 17402

cliniclean.com

Rev 4175-0 (02/2023)

4HRP15INNCTN

NDC 69464-901-15

REF 90515

# CliniClean™

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

## Non-Sterile

Patient Pre-Operative Prep, Surgical Hand Scrub,  
Healthcare Personnel Hand Wash,  
General Skin & Wound Cleanser  
For Single-Use

Net Contents: 50 Single-Use 0.5 fl oz (15 mL) Packettes

DYE  
FREE

# CliniClean™

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

## **Non-Sterile**

Patient Pre-Operative Prep,  
Surgical Hand Scrub,  
Healthcare Personnel Hand Wash,  
General Skin & Wound Cleanser  
For Single-Use

Net Contents:  
50 Single-Use 0.5 fl oz (15 mL) Packettes

**DYE  
FREE**

# CliniClean™

Chlorhexidine Gluconate 4%

Manufactured for:  
HR Pharmaceuticals, Inc.  
York, PA 17402  
[cliniclean.com](http://cliniclean.com)

Rev 4175-0 (02/2023)  
4HRP15INNCTN





NDC 69464-901-15

# CliniClean™

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

Non-Sterile

Patient Pre-Operative Prep, Surgical Hand Scrub,  
Healthcare Personnel Hand Wash,  
General Skin & Wound Cleanser  
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Net Contents: 50 Single-Use 0.5 fl oz (15 mL) Packettes

DYE  
FREE

REF 90515

## 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
- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease
- **patient preoperative skin preparation:** for the preparation of the patient's skin prior to surgery
- **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
- as a preoperative skin preparation of the head or face

## Drug Facts (continued)

### When using this product

- keep out of the eyes, ears and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures 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.

### 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 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 15 seconds
- rinse and dry thoroughly

## Drug Facts (continued)

### Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes
- dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

### 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

### 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.

Lot number and expiration date printed on side of box

4HRP15PACKET

Please refer to outer packaging for directions for use and product warnings.

Manufactured for:  
HR Pharmaceuticals, Inc.  
York, PA 17402  
cliniclean.com  
Rev 4174-0 (02/2023)  
4HRP15PACKET





## CLINICLEAN

chlorhexidine gluconate 4% solution

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>PEG-75 LANOLIN</b> (UNII: 09179OX7TB)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TRIDECYL ALCOHOL</b> (UNII: 8I9428H868)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>COCO DIETHANOLAMIDE</b> (UNII: 92005F972D)	
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0901-15	50 in 1 CARTON	03/23/2023	
1		15 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0116-0901-	118 mL in 1 BOTTLE; Type 0: Not a Combination	03/23/2023	

**Marketing Information**

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

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

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

Revised: 3/2023

Xttrium Laboratories, Inc.