

**CLINICLEAN- chlorhexidine gluconate 4% solution**  
**HR Pharmaceuticals, Inc.**

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

Rev 4175-0 (02/2023)

4HRP04FMBTLLBLA

NDC 69464-901-05

REF 90604

**CliniClean™**  
Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution  
with Foaming Pump

Net Contents: 4 oz. (118 ml)

Manufactured for: 4HRP04FMBTLLBLA  
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
- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease
- **skin wound and general skin cleansing**

#### Warnings

For external use only

### Drug Facts (continued)

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- shock ■ facial swelling
- hives ■ rash

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- in contact with meninges
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#### When using this product

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### Drug Facts (continued)

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

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### Drug Facts (continued)

#### 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

#### Skin wound and general skin cleaning:

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#### Other information

- store at 20-25°C (68-77°F)
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#### Inactive ingredients

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#### Questions or comments?

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**Laundry/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

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69464-901 |
| <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<br>in 100 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>PEG-75 LANOLIN</b> (UNII: 09179OX7TB)                           |          |
| <b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZ N16) |          |
| <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:69464-901-05 | 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** - HR Pharmaceuticals, Inc. (117164328)**Registrant** - Xttrium Laboratories, Inc. (007470579)**Establishment**

| Name                      | Address | ID/FEI    | Business Operations    |
|---------------------------|---------|-----------|------------------------|
| Xttrium Laboratories, Inc |         | 007470579 | manufacture(69464-901) |

Revised: 12/2023

HR Pharmaceuticals, Inc.