

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

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

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
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Rev 4170-0 (02/2023)
4HRP04BTLLBL

NDC 69464-901-04 REF 90104

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Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

Non-Sterile

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Healthcare Personnel Hand Wash,
General Skin & Wound Cleanser
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Lift Here

<p>Drug Facts</p> <p>Active ingredient Chlorhexidine gluconate 4% solution</p> <p>Purpose Antiseptic</p> <p>Uses 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>Questions or comments? Monday through Friday 8:00 AM to 4:30 PM CST call 1-800-587-3721</p>
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<p>Drug Facts (continued)</p> <p>Skin wound and general skin cleansing:</p> <ul style="list-style-type: none"> 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 <p>Other information</p> <ul style="list-style-type: none"> store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F) <p>Inactive ingredients cocamide DEA, fragrance, gucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tidecyl alcohol</p> <p>Questions or comments? Monday through Friday 8:00 AM to 4:30 PM CST call 1-800-587-3721</p> <p>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.</p>	<p>Drug Facts (continued)</p> <p>Warnings For external use only</p> <p>Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> wheezing/difficulty breathing snock facial swelling hives rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product in contact with meningitis in the genital area as a preoperative skin preparation of the head or face <p>When using this product</p> <ul style="list-style-type: none"> 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 <p>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. <p>Surgical hand scrub:</p> <ul style="list-style-type: none"> 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 <p>Healthcare personnel handwash:</p> <ul style="list-style-type: none"> 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 <p>Patient preoperative skin preparation:</p> <ul style="list-style-type: none"> apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel repeat procedure for an additional 2 minutes and dry with a sterile towel
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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
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DYE
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Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

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Healthcare Personnel Hand Wash,
General Skin & Wound Cleanser
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**DYE
FREE**

CliniClean™

Chlorhexidine Gluconate 4%

Manufactured for:
HR Pharmaceuticals, Inc.
York, PA 17402
cliniclean.com

Rev 4175-0 (02/2023)
4HRP15INNCTN



NDC 69464-901-15

CliniClean™

Chlorhexidine Gluconate 4%

Antiseptic/Antimicrobial Solution

Non-Sterile

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DYE
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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
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- as a preoperative skin preparation of the head or face

Drug Facts (continued)

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Questions or comments?

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Monday through Friday
8:00 AM to 4:30 PM CST

Laundering/Cleaning Instructions:

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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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69464-901
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: S38J6RZN16)	
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:69464-901-15	50 in 1 CARTON	03/23/2023	
1		15 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:69464-901-	118 mL in 1 BOTTLE; Type 0: Not a Combination	03/23/2023	

Marketing Information

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

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: 3/2023

HR Pharmaceuticals, Inc.