

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

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 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 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 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.

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 Pharmaceuticals, Inc.

York, PA 17402

clinclean.com

4171 Rev 1

(10/2023)

4HRP08BTLLBLA

<p>NDC 69464-901-08 REF 90208</p> <p>CliniClean™ Chlorhexidine Gluconate 4%</p> <p>Antiseptic/Antimicrobial Solution</p> <p>Net Contents: 8 oz. (237 ml)</p> <p>Manufactured for: 4HRP08BTLLBLA HR Pharmaceuticals, Inc. 4171 Rev 1 York, PA 17402 clinclean.com (10/2023)</p>	
<p>Drug Facts</p> <p>Active ingredient Purpose Chlorhexidine gluconate 4% solution Antiseptic</p> <p>Uses</p> <ul style="list-style-type: none">■ 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 <p>Warnings For external use only</p>	<p>Drug Facts (continued)</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■ shock ■ 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 meninges■ in the genital area <p>When using this product</p> <ul style="list-style-type: none">■ 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
<p>Drug Facts (continued)</p> <ul style="list-style-type: none">■ 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>Drug Facts (continued)</p> <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>Skin wound and general skin cleaning:</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, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol</p> <p>Questions or comments? call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST</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.

6 94640 16108 7

NDC 69464-901-16

REF 90316

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 Pharmaceuticals, Inc.

York, PA 17402

clinclean.com

4172 Rev 1

(10/2023)

4HRP16BTLLBLA

<p>NDC 69464-901-16 REF 90316</p> <p>CliniClean™ Chlorhexidine Gluconate 4%</p> <p>Antiseptic/Antimicrobial Solution</p> <p>Net Contents: 16 oz. (473 ml)</p> <p>Manufactured for: 4HRP16BTLLBLA HR Pharmaceuticals, Inc. 4172 Rev 1 York, PA 17402 clinclean.com (10/2023)</p>	<p>Drug Facts (continued)</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■ shock ■ facial swelling■ hives ■ rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p>	<p>Drug Facts (continued)</p> <ul style="list-style-type: none">■ 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>Drug Facts (continued)</p> <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>Skin wound and general skin cleaning:</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>Drug Facts</p> <p>Active ingredient Purpose Chlorhexidine gluconate 4% solution Antiseptic</p> <p>Uses</p> <ul style="list-style-type: none">■ 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 <p>Warnings For external use only</p>	<p>When using this product</p> <ul style="list-style-type: none">■ 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	<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

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 detergent.

6 94640 16116 2

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 Pharmaceuticals, Inc.

York, PA 17402

clinclean.com

Rev 4171-0 (02/2023)

4HRP32BTLLBL

Drug Facts

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 are 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
- 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.

Drug Facts (continued)

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

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.

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

LAURAMINE OXIDE (UNII: 4F6FC4MI8W)

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	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0901)

Revised: 12/2023

Xttrium Laboratories, Inc.