

ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid
Xttrium Laboratories, Inc.

XTT CVS 4% CHG 8oz, 8oz CA, 16oz, 16oz CA, 18oz, 18oz CA

Chlorhexidine gluconate 4% Solution

Purpose

Antiseptic

Uses

- **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.

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?

1-800-587-3721

Packaging

CVS Health

Compare to the active ingredient in Hibiclens®

NDC 59779-767-08

Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION


Antiseptic / Antimicrobial skin cleanser

For external use only

TAMPER EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

8 fl oz (237 mL)

4CVS08BTLLBLG



Compare to the active ingredient in Hibiclens®
NDC 59779-767-08

Antiseptic Skin Cleanser


CHLORHEXIDINE GLUCONATE 4% SOLUTION

Antiseptic Antimicrobial skin cleanser

For external use only

8 FL OZ (237 mL)

DYE FREE



Drug Facts	Drug Facts (continued)	Drug Facts (continued)
Active ingredient Chlorhexidine gluconate 4% solution Antiseptic	When using this product <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■ repeated general skin cleansing of large body areas should not be done except when advised by a health care provider	Healthcare personnel handwash: <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 Skin wound and general skin cleaning: <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
Uses <ul style="list-style-type: none">■ healthcare personnel handwash: helps reduce bacteria that potentially can cause disease■ skin wound and general skin cleansing	Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.	Other information <ul style="list-style-type: none">■ store at 20-25°C (68-77°F)■ avoid excessive heat above 40°C (104°F)
Warnings For external use only Allergy alert: This product may cause a severe allergic reaction. Symptoms may include: <ul style="list-style-type: none">■ wheezing/difficulty breathing■ shock■ hives■ facial swelling■ rash If an allergic reaction occurs, stop use and seek medical help right away.	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	Inactive ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol
Do not use <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	Directions <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.	Questions? 1-800-587-3721

*This product is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiclens®.

4CVS08BTLLBLG

CAUTION: CLEANING INSTRUCTIONS:
Chlorhexidine gluconate skin cleanser will cause skin irritation if used with other cleaning products, such as bleach. Rinse completely and avoid immediate reagents.

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#864765

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CVS Health

Compare to the active ingredient in Hibiclens®

NDC 59779-767-08

Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION

Antiseptic / Antimicrobial skin cleanser

For external use only

TAMPER EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

8 fl oz (237 mL)

4CVS08LBL4CAD

Compare to the active ingredient in Hibiclens®*

NDC 59779-767-08

Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION

Antiseptic Antimicrobial skin cleanser

For external use only

8 FL OZ (237 mL)

DYE FREE

WARNING: This product can expose you to coconut oil diethanolamine condensate (cocamide diethanolamine), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Drug Facts

Active ingredient Chlorhexidine gluconate 4% solution Antiseptic

Purpose Antiseptic

Uses

- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- skin wound and general skin cleansing

Warnings
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Drug Facts (continued)

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Drug Facts (continued)

Healthcare personnel handwash:

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Other information

- store at 20-25°C (68-77°F)
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Inactive ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

Questions? 1-800-587-3721

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4CVS08BL4CAD

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.

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CVS Health

Compare to the active ingredient in Hibiclens®

NDC 59779-767-16

Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION

Antiseptic / Antimicrobial skin cleanser

For external use only

TAMPER EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

16 fl oz (473 mL)

4CVS16BTLLBLB

Compare to the active ingredient in Hibiclens®*

NDC 59779-767-16

Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION

Antiseptic Antimicrobial skin cleanser

For external use only

16 FL OZ (473 mL)

DYE FREE

Drug Facts

Active ingredient Chlorhexidine gluconate 4% solution Antiseptic

Purpose Antiseptic

Uses

- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- skin wound and general skin cleansing

Warnings
For external use only

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- wheezing/difficulty breathing
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Drug Facts (continued)

When using this product

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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.

Drug Facts (continued)

Healthcare personnel handwash:

- wet hands with water
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Other information

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Inactive ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

Questions? 1-800-587-3721

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4CVS16BTLLBLB

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.

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CVS Health

Comapre to the active ingredient in Hibiclens®

NDC 59779-767-16

Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION


Antiseptic / Antimicrobial skin cleanser

For external use only

TAMPER EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

16 fl oz (473 mL)

4CVS16LBL4CAC



Compare to the active ingredient in Hibiclens®*

NDC 59779-767-16

Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION

Antiseptic Antimicrobial skin cleanser

For external use only

16 FL OZ (473 mL)

DYE FREE

WARNING: This product can expose you to coconut oil diethanolamine condensate (cocamide diethanolamine), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
Active ingredient Chlorhexidine gluconate 4% solution Purpose Antiseptic	When using this product <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■ repeated general skin cleansing of large body areas should not be done except when advised by a health care provider	Healthcare personnel handwash: <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 Skin wound and general skin cleaning: <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
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Directions <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.		Questions? 1-800-587-3721

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4CVS16LBL4CAC

CHLORHEXIDINE GLUCONATE SKIN CLEANSER INSTRUCTIONS: Chlorhexidine gluconate skin cleanser will cause skin irritation if used excessively. Rinse thoroughly with water after each use. Rinse completely and avoid face-chemical irritants.

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CVS Health

Comapre to the active ingredient in Hibiclens®

NDC 59779-767-18

FOAMING

Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION

Antiseptic / Antimicrobial skin cleanser

Clinically proven to reduce bacteria on skin

18 fl oz (532 mL)

For external use only

4CVS18FMBTLLBLA

Inactive Ingredients

Ingredient Name	Strength
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
PEG-75 LANOLIN (UNII: 091790X7TB)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0767-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2011	
2	NDC:0116-0767-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2017	
3	NDC:0116-0767-18	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	08/31/2011	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0767)

Revised: 12/2023

Xttrium Laboratories, Inc.