

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

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

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
8 FL OZ (237 mL)
DYE FREE

Drug Facts
Active ingredient Purpose
Chlorhexidine gluconate 4% solution Antiseptic

Uses
■ **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
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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

Drug Facts (continued)
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
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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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■ thoroughly rinse the area to be cleaned with water
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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

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

4CVS08BTLLBLG
CAUTION: Chlorhexidine gluconate skin cleanser will cause skin irritation if used on damaged skin. Do not use on open wounds, cuts, or abrasions. Bleach completely and avoid mucous membranes.
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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 Purpose
Chlorhexidine gluconate 4% solution Antiseptic

Uses

- **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
- hives
- facial swelling
- 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

Drug Facts (continued)

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.

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
- 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:

- 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? 1-800-587-3721

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

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 Purpose
Chlorhexidine gluconate 4% solution Antiseptic

Uses

- **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
- hives
- facial swelling
- 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

Drug Facts (continued)

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
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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
- 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:

- 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

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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

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)

4CVS16LBL4CAC

CVS Health

Compare 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

CVS Health. Compare to the active ingredient in Hibiclens®
NDC 59779-767-18

Foaming Antiseptic Skin Cleanser
CHLORHEXIDINE GLUCONATE 4% SOLUTION
Antiseptic/Antimicrobial skin cleanser
For external use only
18 FL OZ (532 mL)

Drug Facts
Active ingredient Purpose
Chlorhexidine gluconate 4% solution.....Antiseptic
Uses
■ 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.

Drug Facts (continued)
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

Drug Facts (continued)
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.
Healthcare personnel handwash:
■ wet hands with water
■ dispense 4 full pumps (about 5 mL) of product into cupped hands and wash in a vigorous manner for 15 seconds
■ rinse and dry thoroughly

Drug Facts (continued)
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, triethyl alcohol
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CVS Health
Compare to the active ingredient in Hibiclens®
NDC 59779-767-18
FOAMING
Antiseptic Skin Cleanser
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Clinically proven to reduce bacteria on skin
18 fl oz (532 mL)
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CVS Health. Compare to the active ingredient in Hibiclens®
NDC 59779-767-18

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CHLORHEXIDINE GLUCONATE 4% SOLUTION
Antiseptic/Antimicrobial skin cleanser
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■ wet hands with water
■ dispense 4 full pumps (about 5 mL) of product into cupped hands and wash in a vigorous manner for 15 seconds
■ rinse and dry thoroughly

Drug Facts (continued)
Skin wound and general skin cleansing:
■ thoroughly rinse the area to be cleaned with water
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ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0116-0767 |
| 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: 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 | 01/31/2027 |

| 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)

Revised: 12/2025

Xttrium Laboratories, Inc.