

CARDINAL HEALTH ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 2% solution
Xttrium Laboratories, Inc.

Cardinal Health 2%

Active ingredient

Chlorhexidine gluconate 2% 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 meninges
- in the genital area
- as a preoperative skin preparation of the head or face

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 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.

Surgical hand scrub:

- wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- 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

Patient preoperative skin preparation:

- 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

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

citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

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.

WARNING: This product can expose you to chemicals including cocamide DEA, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov

For Professional and Hospital Use

You may report serious side effects to 1-877-227-3462

Not Made with Natural Rubber Latex

Distributed by

Cardinal Health

Waukegan, IL 60085 USA

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Package Label

NDC: 0116-0113-04

REF AS-2CHGL4

Cardinal Health

Chlorhexidine Gluconate 2% Solution

Single Use Antiseptic

Non Sterile Solution

cardinalhealth.com/symbolsglossary

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4 fl oz (118 mL)

2CHA04BTLLBLC



Drug Facts

| Active ingredient | Purpose |
|---------------------------------------------|----------------|
| Chlorhexidine gluconate 2% solution..... | Antiseptic |

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Lift Here - ZCHA048TUBIC

Drug Facts (continued)

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- in the genital area
- as a preoperative skin preparation of the head or face

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.
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Skin wound and general skin cleansing:

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Drug Facts (continued)

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NDC: 0116-0113-08

REF AS-2CHGL8

Cardinal Health

Chlorhexidine Gluconate 2% Solution

Antiseptic

8 fl oz (237 mL)

2CHA08BTLLBLC

REF AS-2CHGL8



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Antiseptic



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2CHA08TLLBLC

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▲ Lift Here

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CARDINAL HEALTH ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 2% solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0116-0113

| | | | | |
|----------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------|-----------------------------|---------------------------|
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L) | CHLORHEXIDINE GLUCONATE | 2 g in 100 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16) | | | |
| | COCO DIETHANOLAMIDE (UNII: 92005F972D) | | | |
| | WATER (UNII: 059QF0K00R) | | | |
| | CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | | | |
| | LAURAMINE OXIDE (UNII: 4F6FC4MI8W) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0116-0113-04 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2015 | |
| 2 | NDC:0116-0113-08 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2015 | |
| 3 | NDC:0116-0113-16 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2015 | 05/31/2019 |
| 4 | NDC:0116-0113-32 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2015 | 05/31/2019 |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| NDA | NDA019422 | 05/01/2015 | | |

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Xttrium Laboratories, Inc. | | 007470579 | manufacture(0116-0113) |