

APLICARE ANTISEPTIC CHLORHEXIDINE GLUCONATE- chlorhexidine gluconate solution
Aplicare Products, LLC.

1986 Aplicare 4% CHG Solution

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

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients
- in contact with meninges
- in the genital area
- as a preoperative skin prep 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 installed in the middle ear through perforated ear drums.
- 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 the underlying condition makes it necessary to reduce the bacterial population of the skin

Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. This 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 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

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 deg - 25 deg C (68 deg - 77 deg F)
- avoid excessive heat above 40 deg C (104 deg F)

Inactive ingredients

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

Questions or comments?

1-800-760-3236 (Mon.-Fri. 8:30AM - 5:00 PM EST)

4% Chlorhexidine Gluconate

NDC 52380-1986-4

APLICARE
CHLORHEXIDINE
GLUCONATE 4% SOLUTION
ANTISEPTIC

Contains: 4% Chlorhexidine Gluconate
Distributed By: APLICARE, INC.
Meriden CT 06450-7172
www.aplicare.com
Made in U.S.A. L986-0114

FOR EXTERNAL USE ONLY

1100352380198649
Net Contents: 4 fl oz (118 mL)

Drug Facts (continued)

Other Information

- Store at 20-25°C (68-77°F)
- Avoid excessive heat above 40°C (104°F)

Inactive Ingredients: acacia, DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, triethyl alcohol

Questions or comments?
1-800-780-3285 (Mon - Fri, 8:30 AM - 5:00 PM EST)

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Drug Facts

Active Ingredient
chlorhexidine gluconate

Purpose
Antiseptic

Uses

- surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to health-care personnel handwash; helps reduce bacteria that potentially can cause disease
- preoperative skin preparation: for the preparation of the patient's skin
- skin wound and general skin cleaning

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Drug Facts (continued)

Do not use

- if you are allergic to components of products in contact with mucous membranes
- as a preoperative skin preparation of the patient

Warnings

- Keep out of eyes, ears, and mouth. May irritate eyes, ears, and mouth. If irritation occurs, flush with water. If irritation persists, consult your health-care provider for advice on the appropriate treatment.
- Do not use on large areas of the body.
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Directions

- Use with care on preoperative patients or patients with open wounds.
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Drug Facts (continued)

Directions

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APLICARE ANTISEPTIC CHLORHEXIDINE GLUCONATE

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-1986
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
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-1986-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/1998	07/01/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	09/01/1998	07/01/2020

Labeler - Aplicare Products, LLC. (081054904)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(52380-1986)

Revised: 1/2020

Aplicare Products, LLC.