

APLICARE ANTISEPTIC CHLORHEXIDINE GLUCONATE - chlorhexidine gluconate solution

Aplicare, Inc.

Drug Facts

Active ingredient

Chlorhexidine Gluconate 2% solution

Purpose

Surgical hand scrub

Healthcare personnel handwash

Patient preoperative skin preparation

Skin wound and general skin cleansing

Warning

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

Surgical hand scrub

- wet hands and forearms under running 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
- 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

Questions or comments?

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

2% Chlorhexidine Gluconate, 4 oz.

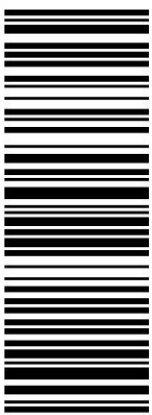
APLICARE, INC.
Meriden, CT 06450-7172
www.aplicare.com
Made in U.S.A.
L319-0206



NDC 52380-1274-4 Reorder No. 82-319

ANTISEPTIC
2% CHLORHEXIDINE
GLUCONATE
SOLUTION

LIFT HERE



(01) 0 0352380 12744 1

4 fl. oz. (118 ml)

Drug Facts

Active ingredient chlorhexidine gluconate 2% solution	Purposes surgical hand scrub healthcare personnel handwash patient preoperative skin preparation skin wound and general skin cleansing
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Uses

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** handwash to help 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
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- in contact with meninges
- in the genital area
- as a preoperative skin preparation of the head or face

-----Panel 3, 2.0625"----- | -----Panel 4, 2.0625"-----

Drug Facts (continued)

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

Drug Facts (continued)

Directions

- wash for an additional 3 minutes with 5 ml of product and rinse under running water
- dry thoroughly

Healthcare personnel handwash

surgical procedures or may cause deafness when inserted 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 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. 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

Surgical hand scrub

- wet hands and forearms under running 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

- wet hands with water
- dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 15 seconds
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Patient preoperative skin preparation

- apply product liberally to surgical site and swab for at least 2 minutes
- 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

Questions or comments?

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

APLICARE ANTISEPTIC CHLORHEXIDINE GLUCONATE

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-1274
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 g

Inactive Ingredients

Ingredient Name	Strength
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Cocamide Diethanolamine (UNII: 92005F972D)	
Hydroxyethyl Cellulose (140 CPS AT 5%) (UNII: 8136Y38GY5)	
Isopropyl Alcohol (UNII: ND2M416302)	
Lauramine Oxide (UNII: 4F6FC4M8W)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-1274-4	120 g in 1 BOTTLE		
2	NDC:52380-1274-8	240 g in 1 BOTTLE		

3	NDC:52380-1274-6	480 g in 1 BOTTLE		
4	NDC:52380-1274-7	960 g in 1 BOTTLE		
5	NDC:52380-1274-9	3785 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019422	09/01/1998	

Labeler - Aplicare, Inc. (107255002)

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare, Inc.		058377631	repack

Revised: 6/2010

Aplicare, Inc.