

APLICARE ANTISEPTIC CHLORHEXIDINE GLUCONATE- chlorhexidine gluconate solution

Aplicare, Inc.

Drug Facts

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

- single use when used for patient preoperative skin preparation
- 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 on 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 with 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

Inactive ingredients

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

Questions or comments?

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

4% Chlorhexidine Gluconate


Drug Facts (continued)

Other information

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

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Questions or comments?
 1-800-763-3238 Mon-Fri, 8:30 AM-5:00 PM EST



CLOROX HEALTHCARE™

CHLORHEXIDINE GLUCONATE 4% SOLUTION

ANTISEPTIC
NON-STERILE SOLUTION
FOR EXTERNAL USE ONLY

4%

30100352380127243

NET CONTENTS: 4 FL OZ (118 mL)

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- skin wound and general skin cleansing

NON-BLEACH

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Drug Facts (continued)

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APPLICARE ANTISEPTIC CHLORHEXIDINE GLUCONATE

chlorhexidine gluconate solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52380-1272
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4K00DY52L)	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: 059QF0K0OR)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-1272-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

2	NDC:52380-1272-8	237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:52380-1272-6	473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:52380-1272-7	946 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:52380-1272-9	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - Aplicare, Inc. (107255002)

Revised: 8/2015

Aplicare, Inc.