

**4% CHG SKIN CLEANSING KIT- fiber, medical, absorbent
Aplicare, Inc.**

Active ingredient

Chlorhexidine Gluconate 4% Solution

Purposes

surgical hand scrub

healthcare personnel handwash

patient preoperative skin preparation

skin wound and general skin cleansing

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

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 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 ear drums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers 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 for 30 seconds
- scrub for 3 minutes with about 5 mL of product with or without a wet brush, paying close attention to the nails, cuticles and interdigital spaces
- rinse thoroughly 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
- dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general 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 POFL 147, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

Questions or comments?

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

4% Chlorhexidine Gluconate, 128 oz

CLOROX HEALTHCARE™
CHLORHEXIDINE GLUCONATE 4% SOLUTION
 ANTISEPTIC NON-STERILE SOLUTION FOR EXTERNAL USE ONLY

NDC 52380-1272-4 Reorder No. 82-286

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NON-BLEACH

Drug Facts (continued)

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, urdecy alcohol

Questions or comments?
 ■ 1-800-763-3236 Mon–Fri, 8:30 AM–5:00 PM (EST)

Lift Here

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 surgery or patient care
 ■ healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
 ■ patient preoperative skin preparation: preparation of the patient's skin prior to surgery
 ■ skin wound and general skin cleansing

NET CONTENTS: 4 FL OZ (118 mL)

Drug Facts (continued)

Warnings
 For external use only

Do not use
 ■ if you are allergic to chlorhexidine gluconate or any other ingredients
 ■ in contact with meningitis
 ■ in the genital area
 ■ as a preoperative skin preparation 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, if introduced 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 healed
 ■ 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 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.

Drug Facts (continued)

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 scrub 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

4% CHG SKIN CLEANSING KIT

fiber, medical, absorbent kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NHRIC:52380-7001
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:52380-7001-0	1 in 1 KIT; Type 1: Convenience Kit of Co-Package		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		2
Part 2	1 BOTTLE	118 mL

Part 1 of 2

NON-COTTON CLEANSING WIPES

fiber, medical, absorbent

Product Information

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	ABC	07/01/2014	

Part 2 of 2

APLICARE ANTISEPTIC CHLORHEXIDINE GLUCONATE

chlorhexidine gluconate solution

Product Information

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: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: 819428H868)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	

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		

Marketing Information

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	ABC	07/01/2014	

Labeler - Aplicare, Inc. (058377631)

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare, Inc.		058377631	pack(52380-7001)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium, Inc.		007470579	manufacture(52380-1272)

Revised: 8/2015

Aplicare, Inc.