

ANTISEPTIC SOLUTION- chlorhexidine gluconate 4% solution
Coloplast Corp

4% Coloplast

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 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 the 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
- 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 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 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 20-25°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, tridecyl alcohol

Questions or comments?

call **1-800-587-3721** Monday through Friday 8:00 AM to 4:30 PM CST

Laundering/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.

Micro-Guard® CHG Solution

NDC 11701-172-52

Chlorhexidine Gluconate 4% Solution Antiseptic

4%

CHG Solution

Antiseptic

Non-Sterile Solution

For Single Use

Manufactured for and Distributed by:

Coloplast Corp, 1601 W River Rd N, Minneapolis, MN 55411 U.S.A.

1-800-533-0464 www.coloplast.us **Product #67770**

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4 fl. oz. (118 mL)

E21-1475

4COL04BTLLBL

Micro-Guard[®] CHG Solution NDC 11701-172-52

Chlorhexidine Gluconate 4% Solution Antiseptic

4%
CHG Solution



**Antiseptic
Non-Sterile Solution**

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4 fl. oz. (118 mL)
4COL04BTL1BL



E21-1475

WARNING: Cancer -
P65Warnings.ca.gov



Drug Facts

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Lift Here

Drug Facts (continued)

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ANTISEPTIC SOLUTION

chlorhexidine gluconate 4% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11701-172
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
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
WATER (UNII: 059QF0KO0R)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11701-172-52	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	07/01/2021	

Labeler - Coloplast Corp (110326675)

Registrant - Xttrium Laboratories, Inc (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc		007470579	manufacture(11701-172)

Revised: 6/2021

Coloplast Corp