

PRE-SCRUB II SURGICAL HAND SCRUB- chlorhexidine gluconate solution solution
BioMed Systems, Inc.

Pre-Scrub II Surgical Hand Scrub

Active Ingredient

Chlorhexidine gluconate 4% Solution

Purpose

Antiseptic

Uses

- **surgical hand scrub:** significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care

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 are allergic to chlorhexidine gluconate or any other ingredient in this product

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury

if permitted to enter or allowed to remain.

- if contact occurs, rinse with cold water right away
- do not use routinely if you have wounds which involve more than the superficial

layers 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


- Use with care in Premature infants under 2 months of age. These products may cause irritation or chemical burns.
- open package
- wet hands and forearms to the elbows with warm water
- clean under nails with nail pick provided. Nails should be maintained with a 1 millimeter free edge
- wet sponge and squeeze to work up lather
- scrub thoroughly for 3 minutes. Paying particular attention to the nails, cuticles and interdigital spaces. Use the brush side to clean the nails, cuticles and interdigital spaces between the fingers and the sponge side to scrub the hands and forearms
- rinse thoroughly with warm water
- scrub for an additional 3 minutes using the sponge side
- discard brush-sponge
- rinse hands and forearms thoroughly and dry with a sterile towel.

Other information

- store between 20-25°C (68-77°F)
- avoid freezing and excessive heat 40°C (104°F)

Inactive ingredients cocamide DEA, fragrance POFL 147, glucono-delta-lactone, isopropyl alcohol 4%, lauramine oxide, PEG-75 lanolin, purified water, USP, tridecyl alcohol

Questions? 800-424-5556 (Monday to Friday 8 AM – 5 PM)

NDC 22884-8103-1	
PRE – SCRUB 	Reorder No: 8103-08
Chlorhexidine Gluconate 4% Solution Surgical Hand Scrub	
Single Use Brush-Sponge and Nail Cleaner	
Drug Facts	
Active ingredient	Purpose

Active ingredient Chlorhexidine gluconate 4% solution.....**Purpose** Antiseptic

Use

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care

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 are allergic to chlorhexidine gluconate or any other ingredient in this product

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter or allowed to remain.
- if contact occurs, rinse with cold water right away
- do not use routinely if you have wounds which involve more than the superficial layers 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

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- open package
- wet hands and forearms to the elbows with warm water
- clean under nails with nail pick provided. Nails should be maintained with a 1 millimeter free edge.
- wet sponge and squeeze to work up a lather
- scrub thoroughly for 3 minutes. Paying particular attention to the nails, cuticles and interdigital spaces. Use the brush side to clean the nails, cuticles and interdigital spaces between the fingers and the sponge side to scrub the hands and forearms.
- rinse thoroughly with warm water
- scrub for an additional 3 minutes using the sponge side
- discard brush-sponge
- rinse hands and forearms thoroughly and dry with a sterile towel

Other information

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

Inactive ingredients cocamide DEA, fragrance POFL 147, glucono-delta-lactone, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, USP, tridecyl alcohol

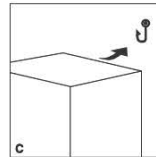
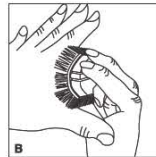
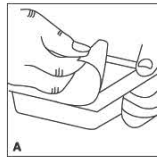
Questions? 800-424-5556 (Monday to Friday 8 AM - 5 PM)

1 Ea. Brush-Sponge, 1 Ea. Nail Cleaner, 1 Ea. Chlorhexidine gluconate 4% solution (Approximate volume 0.8 fl oz (25 mL))
Quantity: 1 Bx., 30 Ea./Bx.

INSTRUCTIONS

To open package, peel lid back at either corner from the end labeled "peel to open". The Lot number on each package is located under peel to open label (Illustration A).
Scrub per Directions above (Illustration B).

Dispenser can be mounted by hanging from hook or Stainless Steel bracket sold separately (Illustration C).



BIOMED

Proudly packaged & Distributed in the U.S.A by:
Biomed Packaging Systems
100 Pearl St., Norwalk, CT 06850

8103-5 (2016) Ph: 1(800) 424-5556



Remove to check level of contents

To dispense, remove this panel.

PRE-SCRUB II SURGICAL HAND SCRUB

chlorhexidine gluconate solution solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:22884-8103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	1 mg in 25 mL

Inactive Ingredients

Ingredient Name	Strength
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
LANOLIN (UNII: 7EV65EAW6H)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:22884-8103-8	30 in 1 CARTON	03/01/1989	
1	NDC:22884-8103-1	25 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019822	03/01/1989	

Labeler - BioMed Systems, Inc. (622463388)**Registrant** - K. W. Griffen Company (622463388)**Establishment**

Name	Address	ID/FEI	Business Operations
Bajaj Medical LLC		078774921	manufacture(22884-8103)

Establishment

Name	Address	ID/FEI	Business Operations
BioMed Systems		622463388	relabel(22884-8103) , repack(22884-8103)

Revised: 12/2021

BioMed Systems, Inc.