

BIOMED

PRE - SCRUB II TM

NDC 22884-8103-1
Item No. 8103-08

(chlorhexidine gluconate) 4% solution

Surgical Hand Scrub Brush-Sponge and nail cleaner
See carton for Drug Facts Labeling L8103-3

Active ingredient

Chlorhexidine gluconate 4% solution..... Antiseptic
Approximate volume 25 mL

Purpose

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

Warnings

Do not use • if you are allergic to chlorhexidine gluconate or any other ingredients in this product • as a patient preoperative skin preparation (especially of the head & face) • in contact with meninges • in the genital area

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 the 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 sponge side • discard brush-sponge • rinse hands and forearms thoroughly and dry with sterile towel

store between 20 -25°C (68-77°F) • avoid excessive heat above 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, triethyl alcohol

Made in the U.S.A by: Biomed Systems, Inc. Norwalk, CT 06850
Order Direct (800) 424-5556 Order Online: KMGiffenpackaging.com

PEEL TO OPEN
Lot No. & Expiration Date embossed on lower peel flap

L8103-3

*Red color indicates where a change has been made.
Pouch label will be printed one color.*

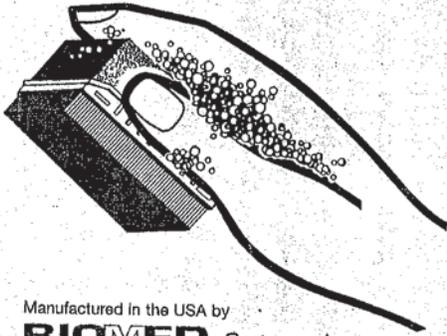
8103-08

**PRE-
SCRUB II™**

(chlorhexidine gluconate) 4% solution

Surgical Hand Scrub
(Brush-Sponge and Nail Cleaner)

Single Use



Manufactured in the USA by
BIOMED Systems, Inc.

Remove to check level of contents.

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

To dispense, remove this panel.

*Dispenser / Carton Label
Face Panel 1*

Dispenser / Carton Label
Left Panel 2

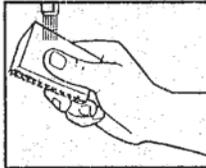
PRE-SCRUB

(chlorhexidine gluconate) 4% solution

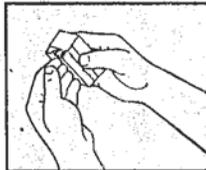
Surgical Hand Scrub (Brush-Sponge and Nail Cleaner)

Single Use

Directions for Use:



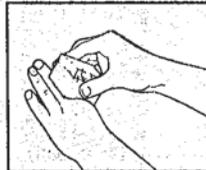
1. Open package and clean under nails with the nail pick provided. Nails should be maintained with a 1 millimeter free edge.



2. Wet hands and forearms to the elbows with warm water.

3. Wet sponge and squeeze to work up lather.

4. Scrub thoroughly for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces. Use the brush side of the product to clean the nails, cuticles, and interdigital spaces. Use the sponge side of the product when scrubbing the hands and forearms.



5. Rinse thoroughly with warm water and repeat scrub for an additional 3 minutes using the sponge side of the product only.

6. Rinse thoroughly and dry with a sterile towel.

Warning

For External Use Only

Other Information

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

Manufactured in the USA by
BIOMED Systems, Inc.
NORWALK, CT 06850
Toll Free: (800) 424-5556

Lot No.:

Exp. Date:



+M08681030828

30 BRUSH-SPONGES
8103-08

Dispenser / Carton
Label

Right Panel 3

PRE-SCRUB 

Drug Facts	
Active ingredient	Purpose
Chlorhexidine Gluconate 4% Solution.....	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	
Do not use	
• if you are allergic to chlorhexidine gluconate or any other ingredients in this product	
• as a patient preoperative skin preparation (especially of the head and face)	
• in contact with meninges • in the genital area	
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 and lasts more than 72 hours	
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 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 22884-8103-2



Made from
recycled paper

Drug Facts

Active ingredient

Chlorhexidine gluconate 4% solution.....

Purpose

Antiseptic

Title *Drug Facts* = 14 point Arial Bold Italics

Bar/hair line thickness=3/4pt

Heading *Active Ingredient* =12 point Arial Bold Italic

Heading *Purpose*=12 point Arial Bold Italic flush left

Text = 10 point, Arial

Bar/hair line thickness=3pt

Uses

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

Heading *Uses* =12 point Arial Bold Italic

Subheading *surgical hand scrub* =10 point Arial Bold

Text = 10 point, Arial

Bar/hair line thickness=3pt

Warnings

For external use only

Heading *Warnings* =12 point Arial Bold Italic

For external use only= 10 pt Arial Bold

Bar/hair line thickness=3/4pt

Subheading **Do not use** =10 point Arial Bold

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients in this product
- as a patient preoperative skin preparation (especially of the head and face)
- in contact with meninges • in the genital area

Text = 10 point, Arial

Bar/hair line thickness=3/4pt

Subheading **When using this product** =10 point Arial Bold

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

Text = 10 point, Arial

Bar/hair line thickness=3/4pt

Subheading **Stop use and ask a doctor if** =10 point Arial Bold

Stop use and ask a doctor if

- irritation, sensitization, or allergic reaction occurs and lasts more than 72 hours

Text = 10 point, Arial

Bar/hair line thickness=3/4pt

Keep out of reach of children. =10 point Arial Bold

Text = 10 point, Arial

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Bar/hair line thickness=3pt

Directions

Heading *Directions* =12 point Arial Bold Italic

- 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 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.

Text = 10 point, Arial

Other information

Bar/hair line thickness=3pt

Heading *Other information* =12 point Arial Bold Italic

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

Text = 10 point, Arial

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

Bar/hair line thickness=3pt

Heading *Inactive ingredients* =12 point Arial Bold Italic

Text = 10 point, Arial

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

Bar/hair line thickness=3pt

Heading *Questions* =12 point Arial Bold Italic

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
01/07/2013