

SCRUB, SCRUB-STAT, FOAM SAFE, MICRO-GUARD- chlorhexidine gluconate solution
AVA, Inc.

4% Chlorhexidine Gluconate Solution
Product Code: 125
AVA, Inc.

Active ingredient

Chlorhexidine gluconate, 4%

Purposes

Surgical hand scrub

Healthcare personnel handwash

Skin wound and general skin cleanser

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
- **skin wound and general cleanser:** helps reduce bacteria on the skin

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 ingredients in this preparation
- as a preoperative skin preparation (especially on the head or 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 placed or kept in the eye during surgical procedures or may cause deafness when instilled in the middle ear through perforated ear drums.
- if contact occurs, rinse with cold water right away
- 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 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 and lasts for 72 hours. 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 product may cause irritation or chemical burns.
- use full strength
- do not dilute

Surgical hand scrub

- remove jewelry
- wet hands and forearms with water and apply 5 mL of the product
- wash/scrub hands and forearms for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces
- rinse thoroughly with water
- wash for an additional 3 minutes with 5 mL of the 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 30 seconds
- rinse and dry thoroughly

Skin wound and general skin cleanser

- thoroughly rinse the area to be cleansed with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently. Rinse thoroughly with water.
- rinse again thoroughly

Other information

- store between 20-25 °C (68-77 °F)
- avoid excessive heat (above 104 °F/40 °C)
- for additional information, see Material Safety Data Sheet (MSDS)
- if swallowed get medical help or contact a Poison Control Center immediately

□Inactive ingredients□

cocamide DEA, cocamine oxide, fragrance, gluconic acid*, gluconolactone*, isopropyl alcohol 4%, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water

*contains one or more of these ingredients

Questions or comments?

call **1.800.581.2528**, 24 hours a day, 7 days a week

Representative label and principal display panel**SCRUB™****Chlorhexidine Gluconate 4% Foaming Solution****ANTIMICROBIAL SKIN CLEANSER****FOR EXTERNAL USE ONLY**

www.SCRUBchg.com

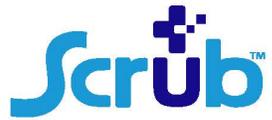
AVA, Inc.

Willowbrook IL 60527

FDA APPROVED**MADE IN THE USA**

WARNING: This product can expose you to cocamide DEA, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov

NDC 42939-125-19**32 fl oz (946 mL)**



Chlorhexidine Gluconate
Foaming Solution

4.0%
ANTIMICROBIAL
skin cleanser

FOR EXTERNAL
USE ONLY
www.SCRUBchg.com
AVA Inc
Willowbrook IL 60527
32 fl oz (946 mL)



3 42939 12519 6

NDC 42939-125-19



<p>Drug Facts</p> <p>Active ingredient Chlorhexidine gluconate solution, 4% Purposes Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser</p> <p>Uses</p> <ul style="list-style-type: none"> 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 skin wound and general skin cleanser: helps reduce bacteria on the skin <p>Warnings For external use only Allergy alert This product may cause a severe allergic reaction. Symptoms may include: <ul style="list-style-type: none"> wheezing/difficulty breathing facial swelling shock hives rash If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> if you are allergic to chlorhexidine gluconate or any other ingredient in this preparation as a patient preoperative skin preparation (especially on the head or face) in contact with meninges in the genital area 		<p>Drug Facts (continued)</p> <p>When using this product</p> <ul style="list-style-type: none"> 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 eardrums. if contact occurs, rinse with cold water right away 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 an underlying condition makes it necessary to reduce the bacterial population of the skin <p>Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. use full strength do not dilute <p>Surgical hand scrub:</p> <ul style="list-style-type: none"> remove jewelry wet hands and forearms with water and apply 5 mL of the product wash/scrub hands and forearms for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> rinse thoroughly with water wash for an additional 3 minutes with 5 mL of the product and rinse under running water dry thoroughly <p>Healthcare personnel handwash:</p> <ul style="list-style-type: none"> wet hands with water dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 30 seconds rinse and dry thoroughly <p>Skin wound and general skin cleanser:</p> <ul style="list-style-type: none"> thoroughly rinse the area to be cleansed with water apply the minimum amount of product necessary to cover the skin or wound area and wash gently. Rinse thoroughly with water. rinse again thoroughly <p>Other information</p> <ul style="list-style-type: none"> store between 20-25°C (68-77°F) avoid excessive heat (above 104°F/40°C) for additional information, see Safety Data Sheet (SDS) if swallowed get medical help or contact a Poison Control Center immediately <p>Inactive ingredients cocamide DEA, cocamine oxide, fragrance, gluconic acid*, glucomolactone*, isopropyl alcohol 4%, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water *contains one or more of these ingredients</p> <p>Questions or comments? call 1.800.581.2528, 24 hours a day, 7 days a week</p>
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⚠️ **WARNING:** This product can expose you to cocamide DEA, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov

Keep from freezing.

GREMED MEDICAL PRODUCTS

FOAM SAFE™

Chlorhexidine Gluconate Liquid Solution

4.0%

ANTIMICROBIAL skin cleanser

FOR EXTERNAL USE ONLY

1 L (1.05 U.S Qt)

U.S. Patent No. Re 33,564

NDC 42939-125-23

GREMED.com

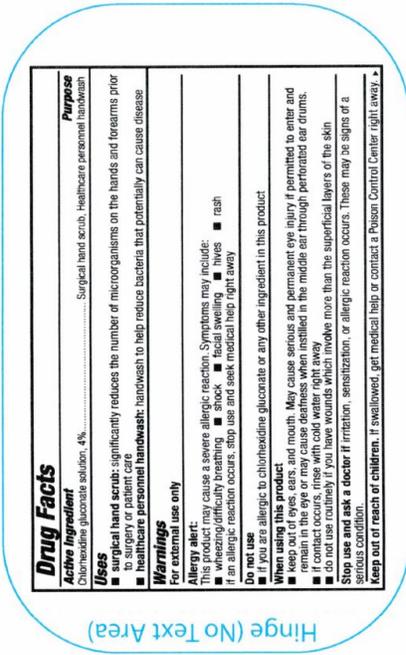
8040 NW 14 St

Doral FL 33126

(Bottle/Container Label)

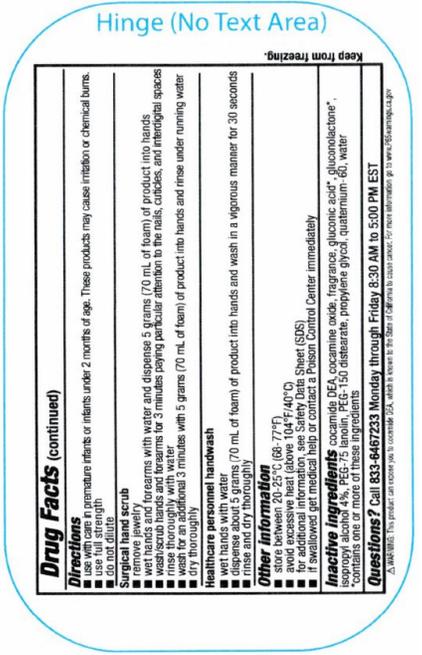


Front



Hinge (No Text Area)

Back
(Inside Front)



Hinge (No Text Area)

GREMED MEDICAL PRODUCTS
FOAM SAFE™
Chlorhexidine Gluconate Liquid Solution
 4.0%
 ANTIMICROBIAL skin cleanser
 FOR EXTERNAL USE ONLY
 1 L (1.05 U.S Qt)
 U.S. Patent No. Re 33,564
 NDC 42939-125-23
 GREMED.com
 8040 NW 14 St
 Doral FL 33126
(Case Label)

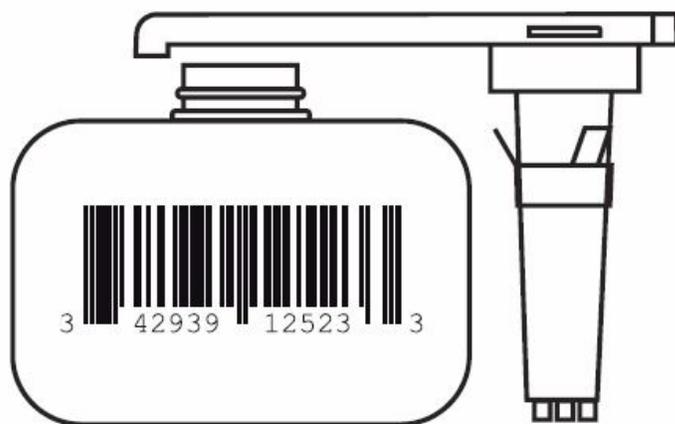
Drug Facts
Active Ingredient:
 Chlorhexidine gluconate solution, 4%
Purpose:
 Surgical hand scrub. Healthcare personnel handwash.
Uses:
 ■ surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care.
 ■ healthcare personnel handwash: handwash to help reduce bacteria that potentially can cause disease.
Warnings:
 For external use only.
Allergy alert:
 This product may cause a severe allergic reaction. Symptoms may include:
 ■ hives ■ facial swelling ■ throat swelling ■ 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 and remain in the eye or may cause deafness when instilled in the middle ear through perforated ear drums.
 ■ do not use on face, neck, or scalp. May cause irritation.
 ■ do not use on deep or large wounds, which may absorb 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.

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.
 ■ use as directed.
 ■ do not dilute.
Surgical hand scrub:
 ■ remove jewelry (earrings, with water and dispense 5 grams (70 mL of foam) of product into hands.
 ■ wash scrub hands and forearms for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces.
 ■ rinse thoroughly with water.
 ■ wash for an additional 3 minutes with 5 grams (70 mL of foam) of product into hands and rinse under running water thoroughly.
Healthcare personnel handwash:
 ■ wet hands with water.
 ■ dispense about 5 grams (70 mL of foam) of product into hands and wash in a vigorous manner for 30 seconds.
 ■ rise and dry thoroughly.
Other information:
 ■ store between 20°-25° (68°-77°F)
 ■ avoid freezing (below 32°/0°C) or heat above 40° (104°/109°F)
 ■ for additional information see Safety Data Sheet (SDS)
 ■ if swallowed get medical help or contact a Poison Control Center immediately.
Inactive ingredients: cocamide DEA, cocamine oxide, fragrance, gluconic acid*, gluconolactone*, isopropyl alcohol 4%, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water.
 *Contains one or more of these ingredients.
Questions? Call 833-8467233 Monday through Friday 8:30 AM to 5:00 PM EST
 ▲ WARNINGS: This product can become toxic to livestock (USA, which is known to the State of California) for more information go to www.foamingsage.com

FOAM SAFE*

4% CHG Surgical Hand Scrub
Chlorhexidine Gluconate 4% w/w

VOIR LE FEUILLET
CONSULTE EL FOLLETO



LOT

GM-13012419

08-2019

01-2021



Use By
Utiliser Avant
Usese Antes



avoid freezing



avoid heating

Do Not Drop
Avoid Freezing
Store at 20-25 °C (68-77 °F)
Avoid Heat Above 104 F° (40° C)

12 1L (1 U.S Qt) Bottle / 12 Bouteilles de 1 L (1 Pinte U.S) /12 Botellas de 1 L (1 cuarto de Galón)
Total 12 L (3 U.S Gal) / Total de 12 L (3 Gal U,S) / Total : 12 L (3 Galones)
12 Dispensign Spouts / 12 Becs verseurs / 12 sifones dosificadores

DISTRIBUITED BY / DISTRIBUE PAR / DISTRIBUIDO - GREMED PRODUCTS - Miami Florida USA
Distribute in Canada By / Distribue ua Canada par / Distribuido en Canada por GREMED

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Phone 833-6467233

SCRUB, SCRUB-STAT, FOAM SAFE, MICRO-GUARD

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42939-125(NDC:47593-468)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE -	CHLORHEXIDINE	40 mg

UNII:R4KO0DY52L)	GLUCONATE	in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMINE OXIDE (UNII: QWA2IZI6FI)	
GLUCONIC ACID (UNII: R4R8J0Q44B)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
QUATERNIUM-33 (UNII: XPS4174QZJ)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42939-125-19	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
2	NDC:42939-125-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
3	NDC:42939-125-22	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
4	NDC:42939-125-21	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
5	NDC:42939-125-23	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019258	07/22/1986	

Labeler - AVA, Inc. (615317075)

Establishment

Name	Address	ID/FEI	Business Operations
AVA, Inc.		615317075	analysis(42939-125) , api manufacture(42939-125) , manufacture(42939-125) , repack(42939-125)

Revised: 11/2023

AVA, Inc.