

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

-----  
**2% Chlorhexidine Gluconate Solution**  
**Product Code: 124**  
**AVA, Inc.**

***Active ingredient***

Chlorhexidine gluconate, 2%

***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 2% 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](http://www.P65Warnings.ca.gov)

**NDC 42939-124-19****32 fl oz (946 mL)**



Chlorhexidine Gluconate  
Foaming Solution

**2.0%**  
ANTIMICROBIAL  
skin cleanser

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



3 42939 124 19 9

NDC 42939-124-19



<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Chlorhexidine gluconate solution, 2% <b>Purposes</b> Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li><b>surgical hand scrub:</b> significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care</li> <li><b>healthcare personnel handwash:</b> handwash to help reduce bacteria that potentially can cause disease</li> <li><b>skin wound and general skin cleanser:</b> helps reduce bacteria on the skin</li> </ul> <p><b>Warnings</b> For external use only <b>Allergy alert</b> This product may cause a severe allergic reaction. Symptoms may include:  <ul style="list-style-type: none"> <li>wheezing/difficulty breathing</li> <li>facial swelling</li> <li>shock</li> <li>hives</li> <li>rash</li> </ul>           If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>if you are allergic to chlorhexidine gluconate or any other ingredient in this preparation</li> <li>as a patient preoperative skin preparation (especially on the head or face)</li> <li>in contact with meninges</li> <li>in the genital area</li> </ul>		<p><b>Drug Facts (continued)</b></p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>if contact occurs, rinse with cold water right away</li> <li>wounds which involve more than the superficial layers of the skin should not be routinely treated</li> <li>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</li> </ul> <p><b>Stop use and ask a doctor</b> if irritation, sensitization or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li> <li>use full strength</li> <li>do not dilute</li> </ul> <p><b>Surgical hand scrub:</b></p> <ul style="list-style-type: none"> <li>remove jewelry</li> <li>wet hands and forearms with water and apply 5 mL of the product</li> <li>wash/scrub hands and forearms for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces</li> </ul>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>rinse thoroughly with water</li> <li>wash for an additional 3 minutes with 5 mL of the product and rinse under running water</li> <li>dry thoroughly</li> </ul> <p><b>Healthcare personnel handwash:</b></p> <ul style="list-style-type: none"> <li>wet hands with water</li> <li>dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 30 seconds</li> <li>rinse and dry thoroughly</li> </ul> <p><b>Skin wound and general skin cleanser:</b></p> <ul style="list-style-type: none"> <li>thoroughly rinse the area to be cleansed with water</li> <li>apply the minimum amount of product necessary to cover the skin or wound area and wash gently. Rinse thoroughly with water.</li> <li>rinse again thoroughly</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store between 20-25°C (68-77°F)</li> <li>avoid excessive heat (above 104°F/40°C)</li> <li>for additional information, see Safety Data Sheet (SDS)</li> <li>if swallowed get medical help or contact a Poison Control Center immediately</li> </ul> <p><b>Inactive ingredients</b> 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><b>Questions or comments?</b> call 1.800.581.2528, 24 hours a day, 7 days a week</p>
--	--	--	--

⚠️ **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

2.0%

ANTIMICROBIAL skin cleanser

FOR EXTERNAL USE ONLY

1 L (1.05 U.S Qt)

U.S. Patent No. Re 33,564

NDC 42939-124-23

GREMED.com

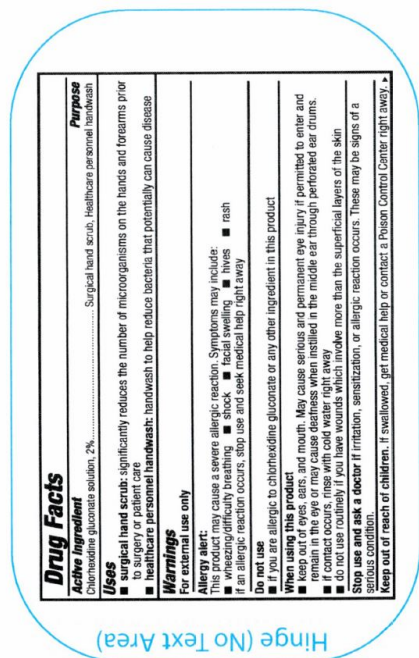
8040 NW 14 St

Doral FL 33126

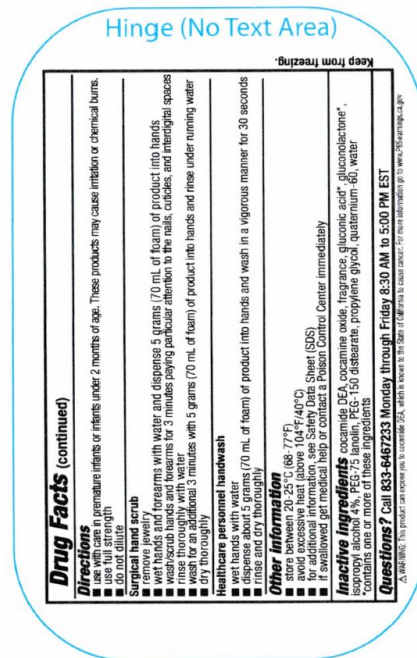
**(Bottle/Container Label)**



Front



Back  
(Inside Front)



**GREMED MEDICAL PRODUCTS**  
**FOAM SAFE™**  
**Chlorhexidine Gluconate Liquid Solution**  
 2.0%  
 ANTIMICROBIAL skin cleanser  
 FOR EXTERNAL USE ONLY  
 1 L (1.05 U.S Qt)  
 U.S. Patent No. Re 33,564  
 NDC 42939-124-23  
 GREMED.com  
 8040 NW 14 St  
 Doral FL 33126  
**(CASE LABEL)**

**FOAM SAFE\***

**2% CHG Surgical Hand Scrub**  
**Chlorhexidine Gluconate 2% w/w**

**VOIR LE FEUILLET**  
**CONSULTE EL FOLLETO**



**LOT**

**GM-13012419**

**08-2019**

**01-2021**



Use By  
 Utiliser Avant  
 Use Before



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

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

\*Registered Trademark or Trademark of Gremed Holding or its affiliates 2008 All rights reserved.  
 \*Maque dePOSE ou marque commerciale de Gremed Holding Ou de ses filiales 2008 Tous droits reserves  
 \*Marca Registrada o marca comercialm de Gremed Holding o sus filiales 2008 Reservados todos los derechos

Phone 833-6467233

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

chlorhexidine gluconate solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42939-124(NDC:47593-467)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E) (CHLORHEXIDINE -	CHLORHEXIDINE	20 mg

UNII:R4KO0DY52L)

GLUCONATE

in 1 mL

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42939-124-19	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
2	NDC:42939-124-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
3	NDC:42939-124-21	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
4	NDC:42939-124-22	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
5	NDC:42939-124-23	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(42939-124) , api manufacture(42939-124) , manufacture(42939-124) , repack(42939-124)

Revised: 11/2023

AVA, Inc.