

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

Chlorhexidine Gluconate
Liquid Foaming Solution, 4%

Antiseptic Skin Cleanser

Product Code: 125
AVA, Inc.

Active ingredient

Chlorhexidine gluconate solution, 4%

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
- **skin wound and general skin 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 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

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 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 healthcare 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 4 full pumps (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 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 4 full pumps (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 again thoroughly

Other information

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

□**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** Monday through Friday 8:00 AM to 5:00 PM CT.

Representative label and principal display panel

Chlorhexidine Gluconate Liquid Foaming Solution

4%

Antiseptic Skin Cleanser

NDC 42939-125-26

4 fl oz (118 mL)

Non-Sterile.

For External Use only.

Manufactured by:

AVA Inc., Willowbrook IL 60527

Made in USA

Issued: 07/2024.

Keep from freezing.

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.

WARNING: This product can expose you to chemicals including amides, coco, n,n-bis(hydroxyethyl) and 2,2'-iminodiethanol which are known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

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Drug Facts	
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Uses	
<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: helps reduce bacteria that potentially can cause disease ■ skin wound and general skin cleansing 	
Warnings	
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Allergy alert	
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Drug Facts (continued)
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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 - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	40 mg in 1 mL

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:42939-125-26	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2024	

Marketing Information

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

Labeler - AVA, Inc. (615317075)

Registrant - 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: 8/2024

AVA, Inc.