

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

Drug Facts

Active ingredient

Chlorhexidine gluconate, 4%

Purpose

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 products 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

FOR EXTERNAL USE ONLY

Distributed By: AVA Inc, 7051 S Adams St, Willowbrook, IL 60527-7592, USA

Distributed To:

**4% CHLORHEXIDINE GLUCONATE ANTISEPTIC
FOAMING SOLUTION**

Drug Facts	
Active ingredient	Purposes
Chlorhexidine gluconate solution, 4%.....	Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser
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: handwash to help reduce bacteria that potentially can cause disease ▪ skin wound and general skin 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:	
<ul style="list-style-type: none"> <li style="width: 25%;">▪ wheezing/difficulty breathing <li style="width: 25%;">▪ shock <li style="width: 25%;">▪ facial swelling <li style="width: 25%;">▪ hives <li style="width: 25%;">▪ rash 	
If an allergic reaction occurs, stop use and seek medical help right away.	
Do not use	
<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 the genital area ▪ in contact with meninges 	
When using this product	
<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 	
Stop 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	
<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 	
Surgical hand scrub:	
<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 ▪ rinse thoroughly with water ▪ wash for an additional 3 minutes with 5 mL of the product and rinse under running water 	

- rinse thoroughly with water
- wash for an additional 5 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 freezing and excessive heat above 40°C (104°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 or comments? call 1.800.581.2528, 24 hours a day, 7 days a week

⚠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.

Lot Number : 002125001
NDC Number : 42939-125-24

Net Contents : 200 kgs
Drum Number : 1 of 12

AVA, Inc.

NDC 42939-125-24

SCRUB™

Chorhexidine Gluconate 4% Antiseptic Foaming Solution

Surgical Hand Scrub, Healthcare Personnel Handwash, and Skin Wound and General Skin Cleanser

Net Content: 200 kgs

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.

www.SCRUBchg.com

AVA, Inc.

7051 South Adams Street

Willowbrook, IL 60527-7592

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:42939-125-24	208000 mL in 1 DRUM; Type 0: Not a Combination Product	07/22/1986	
2	NDC:42939-125-25	1134000 mL in 1 CONTAINER; 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)