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

2% Chlorhexidine Gluconate Liquid Solution Product Code: 127 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 properative 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 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
- washfor 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*, hydroxyethylcellulose, 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% Liquid Solution

ANTIMICROBIAL SKIN CLEANSER

FOR EXTERNAL USE ONLY

www.SCRUBchg.com AVA, Inc. Willowbrook IL 60527

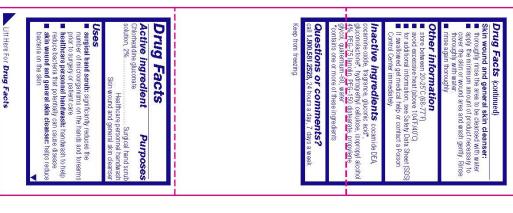
FDA APPROVED MADE IN THE USA

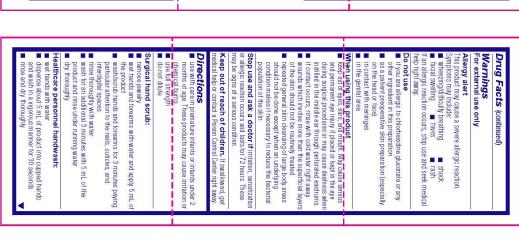
WARNING: This product can expose you to cocamide DEA, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov

NDC 42939-127-01

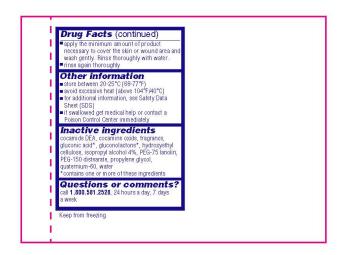
4 fl oz (118 mL)







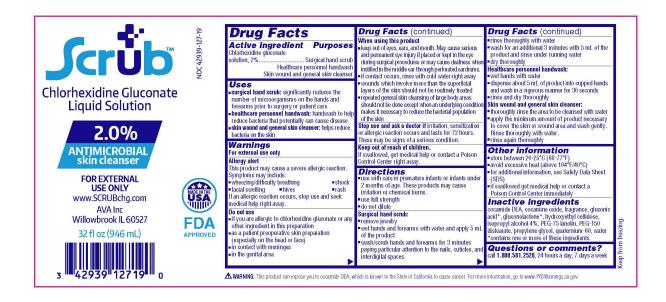








NDC 42939-127-19 32 fl oz (946 mL)



NDC 42939-127-12 128 fl oz (3785 mL)



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

chlorhexidine gluconate solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42939-127(NDC:47593-463)

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
COCO DIETHANOLAMIDE (UNII: 92005F972D)		
COCAMINE OXIDE (UNII: QWA2IZI6FI)		
GLUCONIC ACID (UNII: R4R8J0Q44B)		
GLUCONOLACTONE (UNII: WQ29KQ9POT)		
HYDROXYETHYL CELLULOSE (3000 CPS AT 1%) (UNII: 7Q6P4JN1QT)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
PEG-75 LANOLIN (UNII: 091790X7TB)		
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
QUATERNIUM-33 (UNII: XPS4174QZJ)		
WATER (UNII: 059QF0KO0R)		

Pa	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42939- 127-01	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
2	NDC:42939- 127-02	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
3	NDC:42939- 127-03	750 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
4	NDC:42939- 127-04	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
5	NDC:42939- 127-05	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
6	NDC:42939- 127-06	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
7	NDC:42939- 127-07	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
8	NDC:42939- 127-08	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
9	NDC:42939- 127-09	1000 mL in 1 POUCH; Type 0: Not a Combination Product	07/22/1986	
10	NDC:42939- 127-10	1250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
11	NDC:42939- 127-11	1250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
	NDC:42939- 127-12	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
13	NDC:42939- 127-13	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	

14	NDC:42939- 127-14	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
15	NDC:42939- 127-15	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
16	NDC:42939- 127-16	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
17	NDC:42939- 127-17	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
18	NDC:42939- 127-18	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
19	NDC:42939- 127-19	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
20	NDC:42939- 127-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
21	NDC:42939- 127-21	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
	NDC:42939- 127-22	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
23	NDC:42939- 127-23	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(42939-127), api manufacture(42939-127), manufacture(42939-127), repack(42939-127)

Revised: 11/2023 AVA, Inc.