

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

4% Chlorhexidine Gluconate Liquid Solution
Product Code: 128
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*, 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 Monday through Friday 8:00 AM to 5:00 PM CT.

Representative label and principal display panel**Chlorhexidine Gluconate Liquid Solution**

4%

NDC 42939-128-01

Antiseptic Skin Cleanser

4 fl oz (118 mL)

Non-Sterile.

For External Use only.

**Chlorhexidine
Gluconate
Liquid
Solution**

4%

Antiseptic Skin Cleanser
4 fl oz (118 mL)

Non-Sterile.
For External Use only.

NDC 42939-128-01

Drug Facts

Active ingredient	Purposes
Chlorhexidine gluconate solution, 4%.....	Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser



N 3 42939-12801 2

Base label without leaflet

**Chlorhexidine
Gluconate
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N 3 42939-12801 2

Lift Here For **Drug Facts** ▲

Base label with leaflet

<p>Drug Facts (continued)</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</p> <p>For external use only</p> <p>Allergy alert This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> whistling/difficult breathing facial swelling hives shock rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p>	<p>Drug Facts (continued)</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 meningitis in the genital area <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 procedure 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>Drug Facts (continued)</p> <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>Drug Facts (continued)</p> <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 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 capped hands and wash in a vigorous manner for 30 seconds rinse and dry thoroughly
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<p>Drug Facts (continued)</p> <p>Skin wound and general skin cleanser:</p> <ul style="list-style-type: none"> thoroughly rinse the area to be cleaned 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>Drug Facts (continued)</p> <p>Inactive ingredients</p> <p>cocamide DEA, cocamine oxide, fragrance, gluconic acid*, gluconolactone*, hydroxyethyl cellulose, isopropyl alcohol 4%, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-15, water *contains one or more of these ingredients</p> <p>Questions or comments?</p> <p>Call 1-800-551-2520 Monday through Friday 8:00 AM to 5:00 PM CT</p> <p>Laundrying/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.</p> <p>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.</p>	<p>Chlorhexidine Gluconate Liquid Solution</p> <p>4%</p> <p>Antiseptic Skin Cleanser</p> <p>4 fl oz (118 mL)</p> <p>Drug Facts</p> <p>Active ingredient Purpose</p> <p>Chlorhexidine gluconate solution, 4%.....Surgical hand scrub</p> <p>Healthcare personnel handwash</p> <p>Skin wound and general skin cleanser</p> <p>42939-12801 2</p> <p>Lift Here For Drug Facts</p>
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Base label with leaflet

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.

Keep from freezing.

Revised: 08/2023

Manufactured by:

AVA Inc., Willowbrook IL 60527

Made in USA

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

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42939-128(NDC:47593-464)
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
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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: 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:42939-128-01	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
2	NDC:42939-128-02	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
3	NDC:42939-128-03	750 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
4	NDC:42939-128-04	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
5	NDC:42939-128-05	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
6	NDC:42939-128-06	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
7	NDC:42939-128-07	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
8	NDC:42939-128-08	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
9	NDC:42939-128-09	1000 mL in 1 POUCH; Type 0: Not a Combination Product	07/22/1986	
10	NDC:42939-128-10	1250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
11	NDC:42939-128-11	1250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
12	NDC:42939-128-12	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
13	NDC:42939-128-13	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
14	NDC:42939-128-14	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
15	NDC:42939-128-15	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
16	NDC:42939-128-16	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
17	NDC:42939-128-17	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
18	NDC:42939-128-18	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
19	NDC:42939-128-19	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
20	NDC:42939-128-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	

21	NDC:42939-128-21	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
22	NDC:42939-128-22	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
23	NDC:42939-128-23	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(42939-128) , api manufacture(42939-128) , manufacture(42939-128) , repack(42939-128)

Revised: 5/2024

AVA, Inc.