

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

4% Chlorhexidine Gluconate Solution
Product Code: 125
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*, 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 4% 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

NDC 42939-125-01

4 fl oz (118 mL)

Scrub™

Chlorhexidine Gluconate
Foaming Solution

4.0%
ANTIMICROBIAL
skin cleanser

FOR EXTERNAL
USE ONLY
www.SCRUBchg.com
AVA Inc
Willowbrook, IL 60527

4 fl oz (118 mL)

NDC 42939-125-01



FDA
APPROVED

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

Drug Facts (continued)

- Skin wound and general skin cleanser:**
- 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.

Other information

- 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

Inactive ingredients

cocamide DEA
cocaine oxide, fragrance, gluconic acid*, gluconolactone*, isopropyl alcohol 4%, PEG-7/5 laurdim, PEG-150 distearate, propylene glycol, calcium-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

Keep from freezing.

Drug Facts

Active ingredient

Chlorhexidine gluconate

Solution, 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 skin cleanser:** helps reduce bacteria on the skin

Lift Here For Drug Facts

Drug Facts (continued)

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 preparative skin preparation (especially on the head or face)
- in contact with meningitis
- 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 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 on 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

NDC 42939-125-17

8 fl oz (236 mL)

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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 procedures or may cause death 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>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>Drug Facts (continued)</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>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 cupped hands rinse and dry thoroughly <p>Skin wound and general skin cleanser:</p> <ul style="list-style-type: none"> thoroughly rinse the area to be cleansed with water
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Chlorhexidine Gluconate Foaming Solution

4.0% ANTIMICROBIAL skin cleanser

FOR EXTERNAL USE ONLY



www.ScrubCHG.com
AVA Inc
Willowbrook IL 60527

8 fl oz (236 mL)



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NDC 42939-125-17





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

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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>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</p> <p>Questions or comments? call 1.800.581.2528, 24 hours a day, 7 days a week</p> <p>Keep from freezing</p>

<p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredient</th> <th>Purposes</th> </tr> <tr> <td>Chlorhexidine gluconate solution, 4%.....</td> <td>Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser</td> </tr> </table> <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> <table border="1"> <tr> <td>■ wheezing/difficulty breathing</td> <td>■ shock</td> </tr> <tr> <td>■ facial swelling</td> <td>■ rash</td> </tr> <tr> <td>■ hives</td> <td></td> </tr> </table> <p>If an allergic reaction occurs, stop use and seek medical help right away.</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 	Active ingredient	Purposes	Chlorhexidine gluconate solution, 4%.....	Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser	■ wheezing/difficulty breathing	■ shock	■ facial swelling	■ rash	■ hives		<p>lift here for Drug Facts</p>
Active ingredient	Purposes										
Chlorhexidine gluconate solution, 4%.....	Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser										
■ wheezing/difficulty breathing	■ shock										
■ facial swelling	■ rash										
■ hives											

16 fl oz (473 mL)




Chlorhexidine Gluconate Foaming Solution

4.0%
ANTIMICROBIAL skin cleanser

FOR EXTERNAL USE ONLY

www.SCRUBchg.com
AVA Inc
Willowbrook IL 60527

16 fl oz (473 mL)



3 42939 12518 9

NDC 42939-125-18

Drug Facts

Active ingredient
Chlorhexidine gluconate solution, 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 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:

- wheezing/difficulty breathing
- facial swelling
- shock
- 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

Drug Facts (continued)

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 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 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

Drug Facts (continued)

- 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 at room temperature (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

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 1.800.581.2928, 24 hours a day, 7 days a week

Keep from freezing

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 42939-125-12

128 fl oz (3785 mL)



Chlorhexidine Gluconate Foaming Solution

4.0%
ANTIMICROBIAL skin cleanser

FOR EXTERNAL USE ONLY

128 fl oz (3785 mL)




Drug Facts

Active ingredient
Chlorhexidine gluconate solution, 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
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Warnings

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- hives
- rash

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- as a patient preoperative skin preparation (especially on the head or face)
- in contact with meninges
- in the genital area

Drug Facts (continued)

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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

Drug Facts (continued)

- rinse thoroughly with water
- wash for an additional 3 minutes with 5 mL of the product
- 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 at room temperature (20-25°C (68-77°F))
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cocamide DEA, cocamine oxide, fragrance, gluconic acid*, gluconolactone*, isopropyl alcohol 4%, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water
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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
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)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42939-125-01	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
2	NDC:42939-125-02	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
3	NDC:42939-125-03	750 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
4	NDC:42939-125-04	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
5	NDC:42939-125-05	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
6	NDC:42939-125-06	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
7	NDC:42939-125-07	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
8	NDC:42939-125-08	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
9	NDC:42939-125-09	1000 mL in 1 POUCH; Type 0: Not a Combination Product	07/22/1986	
10	NDC:42939-125-10	1250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
11	NDC:42939-125-11	1250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
12	NDC:42939-125-12	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
	NDC:42939-125-13	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

13	NDC:42939-125-13	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
14	NDC:42939-125-14	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
15	NDC:42939-125-15	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
16	NDC:42939-125-16	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
17	NDC:42939-125-17	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
18	NDC:42939-125-18	473 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(42939-125) , api manufacture(42939-125) , manufacture(42939-125) , repack(42939-125)

Revised: 11/2023

AVA, Inc.