

ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate solution
AVA, Inc.

Antiseptic Skin Cleanser
(Chlorhexidine Gluconate 4% Solution)

Drug Facts

Active ingredient

Chlorhexidine gluconate 4% solution

Purposes

surgical hand scrub
healthcare personnel handwash
patient preoperative skin preparation
skin wound and general skin cleansing

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
- **patient preoperative skin preparation:** for the preparation of the patient's skin prior to surgery
- **skin wound and general skin cleansing**

Warnings

For external use only

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients
- in contact with meninges
- in the genital area
- as a preoperative skin preparation of the head or face

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 the 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. 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 under running water
- scrub for 3 minutes with 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
- wash for an additional 3 minutes with 5 ml of 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 15 seconds
- rinse and dry thoroughly

Patient preoperative skin preparation

- apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general skin cleansing

- 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 again thoroughly

Other information

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

Inactive ingredients

fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol.

Questions or comments?

Call 1-855-552-8274

Manufactured by:

AVA, Inc.

7051 S. Adams St.

Willowbrook, IL 60527

PRINCIPAL DISPLAY PANEL - 947 mL Bottle Label

NDC 42939-102-04

ANTISEPTIC SKIN CLEANSER

(Chlorhexidine Gluconate 4% Solution)

ANTISEPTIC/ANTIMICROBIAL SKIN CLEANSER

FOR EXTERNAL USE ONLY

32 fl.oz. (974 mL)

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING

AVA Incorporated

Lot:

Exp:



Drug Facts	
Active ingredient Chlorhexidine gluconate 4% solution	Purpose Antiseptic
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 ■ patient preoperative skin preparation: for the preparation of the patient's skin prior to surgery ■ skin wound and general skin cleansing 	
Warnings	
For external use only	
Do not use	
<ul style="list-style-type: none"> ■ if you are allergic to chlorhexidine gluconate or any other ingredients ■ in contact with meninges ■ in the genital area ■ as a preoperative skin preparation of the head or face 	
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 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 the 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. 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.	

Drug Facts (continued)
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.
Surgical hand scrub:
<ul style="list-style-type: none"> ■ wet hands and forearms under running water ■ scrub for 3 minutes with 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 ■ wash for an additional 3 minutes with 5 mL of product and rinse under running water ■ dry thoroughly
Healthcare personnel handwash:
<ul style="list-style-type: none"> ■ wet hands with water ■ dispense about 5 mL of product into cupped hands and wash in a vigorous manner for about 15 seconds ■ rinse and dry thoroughly
Patient preoperative skin preparation:
<ul style="list-style-type: none"> ■ apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel ■ repeat procedure for an additional 2 minutes and dry with a sterile towel
Skin wound and general skin cleansing:
<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 again thoroughly
Other information
<ul style="list-style-type: none"> ■ store at 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F)
Inactive ingredients
fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol.
Questions or comments? call 1-855-552-8274
Manufactured by: AVA, Inc. 7051 S. Adams St. Willowbrook, IL 60527

ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42939-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8 E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
HYDROXYETHYL CELLULOSE (1500 MPAS AT 1%) (UNII: L605B5892V)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
WATER (UNII: 059QF0K00R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42939-102-04	947 mL in 1 BOTTLE		
2	NDC:42939-102-03	473 mL in 1 BOTTLE		
3	NDC:42939-102-02	237 mL in 1 BOTTLE		
4	NDC:42939-102-01	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
export only		12/06/2012	

Labeler - AVA, Inc. (615317075)

Registrant - AVA, Inc. (615317075)

Establishment

Name	Address	ID/FEI	Business Operations
AVA, Inc.		615317075	manufacture(42939-102)