

CHLORHEXIDINE GLUCONATE- chlorhexidine gluconate solution
Rising Pharma Holdings, Inc.

Drug Facts

Active ingredients

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
- 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 patient 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 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*, 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 1-884-874-7464 Monday through Friday 8:00 AM to 5:00 PM EST

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

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.

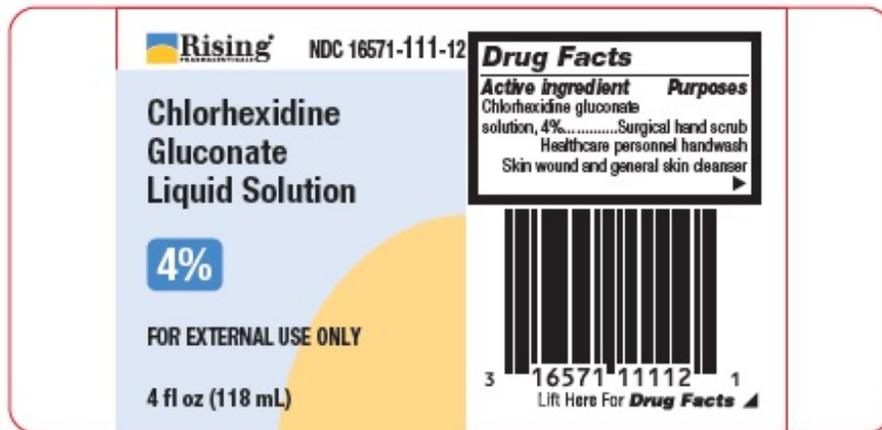
Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Keep from freezing.

Chlorhexidine Gluconate Liquid Solution

NDC:16571-111-12; 118 mL in 1 BOTTLE



<p>Drug Facts (continued)</p> <p>Uses</p> <ul style="list-style-type: none"> • surgical hand scrubs: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care • healthcare personnel handwashes: 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</p> <p>This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> • wheezing/difficulty breathing • facial swelling • hives • rash • shock <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 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 	<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.</p> <p>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 cupped 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 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 <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-60, water *contains one or more of these ingredients</p> <p>Questions or comments?</p> <p>Call 1-844-874-7464 Monday through Friday 8:00 AM to 5:00 PM EST</p> <p>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.</p> <p>WARNING: This product can expose you to chemicals including amides, coco, n,n-bis(hydroxyethyl) and 2,2'-iminoethanol which are known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.</p> <p>Keep from freezing. Issued: 07/2023</p>	<p>Rising NDC 16571-111-12</p> <p>Chlorhexidine Gluconate Liquid Solution</p> <p>4%</p> <p>FOR EXTERNAL USE ONLY</p> <p>8 fl oz (118 mL)</p> <p>Drug Facts</p> <p>Active ingredient Purposes</p> <p>Chlorhexidine gluconate solution, 4%.....Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser</p>  <p>3 16571 11124 1</p> <p>Lift Here For Drug Facts</p> <p><small>Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ 08816</small></p>
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Chlorhexidine Gluconate Liquid Solution

NDC:16571-111-24; 236 mL in 1 BOTTLE

<p>Rising NDC 16571-111-24</p> <p>Chlorhexidine Gluconate Liquid Solution</p> <p>4%</p> <p>FOR EXTERNAL USE ONLY</p> <p>8 fl oz (236 mL)</p>	<p>Drug Facts</p> <p>Active ingredient Purposes</p> <p>Chlorhexidine gluconate solution, 4%.....Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser</p>  <p>3 16571 11124 4</p> <p>Lift Here For Drug Facts</p>
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<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</p> <p>This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> wheezing/difficulty breathing shock facial swelling hives 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 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 	<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.</p> <p>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 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 <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-60, water *contains one or more of these ingredients</p> <p>Questions or comments?</p> <p>Call 1-844-874-7464 Monday through Friday 8:00 AM to 5:00 PM EST</p> <p>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.</p> <p>WARNING: This product can expose you to chemicals including amides, coco, n,n-bis(hydroxyethyl) and 2,2'-iminoethanol which are known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.</p> <p>Keep from freezing. Issued: 07/2023</p>	<p>Rising NDC 16571-111-24</p> <p>Chlorhexidine Gluconate Liquid Solution</p> <p>4%</p> <p>FOR EXTERNAL USE ONLY</p> <p>8 fl oz (236 mL)</p> <p>Drug Facts</p> <p>Active ingredient Purposes</p> <p>Chlorhexidine gluconate solution, 4%.....Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser</p>  <p>3 16571 11124 4</p> <p>Lift Here For Drug Facts</p> <p><small>Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ 08816</small></p>
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Chlorhexidine Gluconate Liquid Solution

NDC:16571-111-48; 473 mL in 1 BOTTLE



NDC 16571-111-48

Chlorhexidine Gluconate Liquid Solution

4%

FOR EXTERNAL USE ONLY

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Keep from freezing.
Revised: 01/2026

16 fl oz (473 mL)



Drug Facts

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

Purposes

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
- 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 preoperative 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 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. ▶

Drug Facts (continued)

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)
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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.

Chlorhexidine Gluconate Liquid Solution

NDC:16571-111-95; 946 mL in 1 BOTTLE



NDC 16571-111-95

Chlorhexidine Gluconate Liquid Solution

4%

FOR EXTERNAL USE ONLY

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Keep from freezing.
Issued: 07/2023

32 fl oz (946 mL)



Drug Facts

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

Purposes

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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Drug Facts (continued)

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- use full strength
- do not dilute

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- remove jewelry
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Skin wound and general skin cleanser:

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- rinse again thoroughly

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CHLORHEXIDINE GLUCONATE

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16571-111
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)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
GLUCONIC ACID (UNII: R4R8J0Q44B)	
HYDROXYETHYL CELLULOSE (3000 CPS AT 1%) (UNII: 7Q6P4JN1QT)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
QUATERNIUM-33 (UNII: XPS4174QZJ)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16571-111-12	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2023	
2	NDC:16571-111-24	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2023	
3	NDC:16571-111-48	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2023	
4	NDC:16571-111-95	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019258	07/26/2023	

Revised: 2/2026

Rising Pharma Holdings, Inc.