

**MAXICLENS CHLORHEXIDINE GLUCONATE LIQUID SOLUTION, 4%-
chlorhexidine gluconate solution
Henry Schein, Inc.**

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
- 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 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 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
- 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*, hydroxyethyl cellulose, 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 EST

NDC 0404-0175-02

Maxiclens™

Antiseptic Skin Cleanser

(Chlorhexidine Gluconate 4%)

FOR EXTERNAL USE ONLY

Distributed By

HENRY SCHEIN INC.

135 Duryea Road

Melville, NY 11747 USA

Net Contents

32 fl oz (1 qt)(946-mL)

Made in U.S.A.




Product Made in U.S.A.

Keep from freezing.

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 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

REF 570-3268 NDC 0404-0175-02	 HENRY SCHEIN® Maxiclens™ Antiseptic Skin Cleanser (Chlorhexidine Gluconate 4%)		
 FOR EXTERNAL USE ONLY	Drug Facts Active ingredient Purposes Chlorhexidine gluconate solution, 4%..... Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser	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	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
Net Contents 32 fl oz (1 qt)(946-mL) Made in U.S.A. Distributed By HENRY SCHEIN INC. 135 Duryea Road Melville, NY 11747 USA	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	■ 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.	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
 3 04040 17502 6	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.	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	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*, hydroxyethyl cellulose, isopropyl alcohol 4%, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water *contains one or more of these ingredients
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MAXICLENS CHLORHEXIDINE GLUCONATE LIQUID SOLUTION, 4%

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0404-0175
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)	
HYDROXYETHYL CELLULOSE (3000 CPS AT 1%) (UNII: 7Q6P4JN1QT)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
QUATERNIUM-33 (UNII: XPS4174QZJ)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLUCONIC ACID (UNII: R4R8J0Q44B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-0175-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019258	11/17/2021	

Labeler - Henry Schein, Inc. (012430880)