

ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% solution

Henry Schein, Inc.

Maxiclens

Active ingredient

Chlorhexidine gluconate 4% solution

Purpose

Antiseptic

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
- **skin wound and general skin cleansing**

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 or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with the meninges
- in the genital area

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye 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 advised by a health care provider

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 with 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

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

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

Questions or comments?

call **1-800-587-3721** Monday through Friday 8:00 AM to 4:30 PM CST

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

Rev 7/2018

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Rev 11/2018

431-0032

Henry Schein®

Maxiclens

Antiseptic Skin Cleanser

(Chlorhexidine Gluconate 4%)

FOR EXTERNAL USE ONLY

Net Contents

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

Made in U.S.A
Distributed By
HENRY SCHEIN INC.
135 Duryea Road
Melville, NY 11747 USA
4MAX32BTLLBL


Content of Labeling

The image shows a product label for Maxiclens Antiseptic Skin Cleanser. The label features a blue vertical bar on the left side with a circular seal that reads "HENRY SCHEIN SEAL OF EXCELLENCE". The main text on the label includes "HENRY SCHEIN" with a logo, "NDC 0404-1061-32 431-0032", "Maxiclens™", "Antiseptic Skin Cleanser", and "(Chlorhexidine Gluconate 4%)". A blue water drop icon is positioned above the text "FOR EXTERNAL USE ONLY". To the right of the drop is a barcode with the number "*+H658431003204*" printed vertically. At the bottom left, it states "Net Contents 32 fl oz (1 qt)(946-mL) Made in U.S.A.". At the bottom right, it lists "Distributed By HENRY SCHEIN INC. 135 Duryea Road Melville, NY 11747 USA". The code "4MAX32BTLLBL" is printed at the very bottom left of the label area.


HENRY SCHEIN® NDC 0404-1061-32
431-0032

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(Chlorhexidine Gluconate 4%)



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32 fl oz (1 qt)(946-mL)
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Drug Facts (continued)

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Package label and principal display panel

NDC 0404-1061-01

431-0099

HENRY SCHEIN ®

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Distributed By

HENRY SCHEIN INC.

135 Duryea Road

Melville, NY 11747 USA

4MAX1GBTLLBL


NDC 0404-1061-01
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HENRY SCHEIN®
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Antiseptic Skin Cleanser
(Chlorhexidine Gluconate 4%)



FOR EXTERNAL USE ONLY



+H65843100990H

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chlorhexidine gluconate 4% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0404-1061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
COCO DIETHANOLAMIDE (UNII: 92005F972D)	

GLUCONOLACTONE (UNII: WQ29KQ9POT)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE OXIDE (UNII: 4F6FC4M18W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
WATER (UNII: 059QF0K00R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-1061-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2003	
2	NDC:0404-1061-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	04/02/2003	

Labeler - Henry Schein, Inc. (012430880)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories		007470579	manufacture(0404-1061)

Revised: 11/2018

Henry Schein, Inc.