

ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid
Meijer Distribution, Inc.

Meijer 4%

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.

Stop use and ask doctor if

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

Do not use

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

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 vigorous manner for about 15 seconds
- rinse and dry thoroughly

Skin wound and normal 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

Other safety information

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. Rinse completely and use only non-chlorine detergents.

DIST. BY MEIJER DISTRIBUTION, INC.

GRAND RAPIDS, MI 49544

www.meijer.com

*This product is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiclens®.

Package label and principal display panel

NDC 41250-162-08

Compare to the active ingredient in Hibiclens®*

Reduces bacteria on the skin

Antiseptic Skin Cleanser

Chlorhexidine Gluconate 4% Solution

Antiseptic/Antimicrobial Skin Cleanser

FOR EXTERNAL USE ONLY

Dye Free

8 FL OZ (237 mL)

TAMPER EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING.

4MEI08BTLLBLD



NDC 41250-162-08
Compare to
Hibiclens®*
active ingredient

antiseptic skin cleanser

(Chlorhexidine Gluconate 4% Solution)

Antiseptic/Antimicrobial Skin Cleanser

REDUCES BACTERIA ON THE SKIN
DYE FREE

**TAMPER EVIDENT: DO NOT USE
IF SHRINK SEAL NECKBAND IS
BROKEN OR MISSING**

FOR EXTERNAL USE ONLY

8 fl oz (237 mL)

▲ Lift Here

*This product is not manufactured
or distributed by Regent Medical
Limited, owner of the registered
trademark Hibiclens®.

PID 3420119



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GRAND RAPIDS, MI 49544
www.meijer.com



4MEI08BTLBLD

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Chlorhexidine gluconate 4% solution	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

Drug Facts (continued)

Warnings

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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 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 about 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



Drug Facts (continued)

Other information

- Store at 20-25°C (68-77°F)
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Inactive ingredients

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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.

NDC 41250-162-16

Compare to Hibiclens active ingredient

meijer

antiseptic

Drug Facts (continued)

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- 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 about 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



Drug Facts (continued)**Other information**

- store at 20-25°C (68-77°F)
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ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-162
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a	02/25/2021	

1	162-08	Combination Product	03/23/2021	
2	NDC:41250-162-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2014	
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	NDA	NDA019125	01/01/2014	

Labeler - Meijer Distribution, Inc. (006959555)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(41250-162)

Revised: 3/2021

Meijer Distribution, Inc.