

## **HIBICLENS- chlorhexidine gluconate solution**

### **Molnlycke Health Care**

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#### **Hibiclens, 4% CHG**

Chlorhexidine gluconate solution 4.0% w/v

Antiseptic

#### **Uses**

- antimicrobial skin cleanser helps to reduce bacteria that potentially can cause disease
- for skin wound and general skin cleansing
- surgical hand scrub
- healthcare personnel handwash

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 contact occurs in any of these areas, rinse with cold water right away
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general 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.
- *skin wound and general skin cleansing.* Thoroughly rinse the area to be cleansed with water. Apply the minimum amount of the product necessary to cover the skin or wound area and wash gently. Rinse thoroughly.
- *surgical hand scrub.* Wet hands and forearms with water. Scrub for 3 minutes with about 5mL of the product with a brush. Rinse thoroughly under running water. Repeat. Dry thoroughly.
- *healthcare personnel handwash.* Wet hand with water. Dispense about 5mL of the product into cupped hands and wash in a vigorous manner for 15 seconds. Rinse and dry thoroughly.

## Other information

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

fragrance, gluconolactone, isopropyl alcohol 4% w/v, lauramine oxide, poloxamer 237, purified water and red 40

## Questions?

1-800-843-8497

<p>NDC 0234-0575-04</p> <p><b>HIBICLENS</b><sup>®</sup></p> <p>Chlorhexidine Gluconate Solution 4% w/v</p> <p><b>ANTISEPTIC SKIN CLEANSER</b></p> <p>Helps reduce bacteria that potentially can cause disease</p> <p>Mölnlycke</p> <p>4 fl oz (118 mL)</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose</b> Chlorhexidine gluconate solution 4% w/v.....Antiseptic</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ antimicrobial skin cleanser helps reduce bacteria that potentially can cause disease</li> <li>■ for skin wound and general skin cleansing</li> <li>■ surgical hand scrub</li> <li>■ healthcare personnel handwash</li> </ul> <p><b>Warnings</b> <b>For external use only</b></p> <p><b>Allergy alert:</b> This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> <li>■ wheezing/difficulty breathing</li> <li>■ shock</li> <li>■ facial swelling</li> <li>■ hives</li> <li>■ rash</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product</li> <li>■ in contact with the meninges</li> <li>■ in the genital area</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ 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</li> <li>■ if contact occurs in any of these areas, rinse with cold water right away</li> <li>■ wounds which involve more than the superficial layers of the skin should not be routinely treated</li> <li>■ repeated general cleansing of large body areas should not be done except when advised by a health care provider</li> </ul> <p><b>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs.</b> These may be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li> </ul>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>■ <i>skin wound and general skin cleansing.</i> Thoroughly rinse the area to be cleansed with water. Apply the minimum amount of the product necessary to cover the skin or wound area and wash gently. Rinse thoroughly.</li> <li>■ <i>surgical hand scrub.</i> Wet hands and forearms with water. Scrub for 3 minutes with about 5mL of the product with a brush. Rinse thoroughly under running water. Repeat. Dry thoroughly.</li> <li>■ <i>healthcare personnel handwash.</i> Wet hands with water. Dispense about 5mL of the product into cupped hands and wash in a vigorous manner for 15 seconds. Rinse and dry thoroughly.</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store between 20-25°C (68-77°F)</li> <li>■ avoid excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive ingredients</b> fragrance, gluconolactone, isopropyl alcohol 4% w/v, lauramine oxide, poloxamer 237, purified water and red 40</p> <p><b>Questions? 1-800-843-8497</b></p>	<p>Lot number and expiration date printed on bottom of container. Laundering/Cleaning Instructions. Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products. Rinse completely and use only non-chlorine detergents.</p> <p>The Mölnlycke Health Care, Hibi, HibiClen, and HibiStat names and respective logos are registered globally to one or more of the Mölnlycke Health Care Group of Companies. Distributed by Mölnlycke Health Care, US LLC, Peachtree Corners, Georgia 30092 ©2022 Mölnlycke Health Care AB. All rights reserved. 5200776-00-1</p> <p><b>FPO UPC</b> <b>7332551065690</b></p>
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NDC 0234-0575-04

**HIBICLENS.**  
Chlorhexidine Gluconate  
Solution 4% w/v  
**ANTISEPTIC  
SKIN CLEANSER**



PERSISTENT EFFECT    GREAT FOR HAND HYGIENE    GENERAL SKIN CLEANING



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For more information go to  
[www.mylanlycke.com](http://www.mylanlycke.com) SDC0485-05-1



ONE 4 fl oz (118 mL) BOTTLE

NDC 0234-0575-04

**HIBICLENS.**  
Chlorhexidine Gluconate  
Solution 4% w/v  
**ANTISEPTIC  
SKIN CLEANSER**

NDC 0234-0575-04

**HIBICLENS.**  
Chlorhexidine Gluconate  
Solution 4% w/v  
**ANTISEPTIC  
SKIN CLEANSER**



PERSISTENT EFFECT    GREAT FOR HAND HYGIENE    GENERAL SKIN CLEANING

**Drug Facts**

**Active ingredient**  
Chlorhexidine gluconate solution 4% w/v

**Purpose**  
Antiseptic

**Uses**  
Mylanlycke skin cleanser helps reduce bacteria that normally can cause disease.  
Mylanlycke skin cleanser is used for:  
■ Surgical hand scrub  
■ Antiseptic personal handwash

**Warnings**  
**For external use only**

**Warnings**  
This product may cause a severe allergic reaction. Stop use and get medical help if you have:  
■ Difficulty breathing    ■ Shock    ■ Facial swelling  
■ Hives    ■ Rash  
If an allergic reaction occurs, stop use and seek medical help right away.

**Do not use**  
Do not use on the patient's allergy to chlorhexidine gluconate or any other ingredient in this product.  
Do not use with the emollient. ■ In the genital area

**When using this product**  
Wash and dry, dry, and scrub. May cause redness and permanent eye injury if permitted to enter and remain in the eye or any color patches when applied to the middle or through perforated eardrums.  
Do not contact with eyes or mucous membranes. Rinse with cold water right away.  
Do not use on irritated skin.  
■ Irritation of large body areas should not be done except when advised by health care provider.  
Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. There 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 to premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.  
Use for wound and general skin cleansing. Thoroughly rinse the area to be treated with water. Apply the minimum amount of the product necessary to cover the skin or wound area and wash gently. Rinse thoroughly.  
Bleach or bleach fumes: Wet hands and forearms with water. Scrub for 1 minute with about 1/2 oz of the product with a scrub. Rinse thoroughly under running water. Repeat. Dry thoroughly.  
■ Do not use on open wounds or abrasions. Rinse area with water. Rinse thoroughly. Do not use on the face.  
■ Rinse and dry thoroughly.

**Other information**  
■ Store between 20° to 25° (68° to 77°).  
■ Avoid excessive heat above 40° C (104° F).

**Inactive ingredients**  
Fragrance, glycerol, polyethylene glycol, alcohol 16%, benzalkonium chloride, polyethylene glycol, water and red 40.

**Questions?** 1-800-645-8487

NDC 0234-0575-08

# HIBICLENS®

Chlorhexidine Gluconate  
Solution 4% w/v

ANTISEPTIC  
SKIN CLEANSER



PERSISTENT  
EFFECT



GREAT FOR  
HAND HYGIENE



GENERAL SKIN  
CLEANSING

Helps reduce bacteria that potentially can cause disease

Mölnlycke®

8 fl oz (236 mL)

## Drug Facts

**Active ingredient**  
Chlorhexidine gluconate  
solution 4% w/v..... Antiseptic

### Purpose

- Uses**
- antimicrobial skin cleanser helps reduce bacteria that potentially can cause disease
  - for skin wound and general skin cleansing
  - surgical hand scrub
  - healthcare personnel handwash

### 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

## Drug Facts (continued)

- if contact occurs in any of these areas, rinse with cold water right away
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general 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.
- skin wound and general skin cleansing.** Thoroughly rinse the area to be cleansed with water. Apply the minimum amount of the product necessary to cover the skin or wound area and wash gently. Rinse thoroughly.
- surgical hand scrub.** Wet hands and forearms with water. Scrub for 3 minutes with about 5mL of the product with a brush. Rinse thoroughly under running water. Repeat. Dry thoroughly.
- healthcare personnel handwash.** Wet hands with water. Dispense about 5mL of the product into cupped hands and wash in a

## Drug Facts (continued)

vigorous manner for 15 seconds. Rinse and dry thoroughly.

### Other information

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

### Inactive ingredients

fragrance, gluconolactone, isopropyl alcohol 4% w/v, lauramine oxide, poloxamer 237, purified water and red 40

### Questions? 1-800-843-8497

Lot number and expiration date printed on bottom of container. Laundering/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine bleaching products. Rinse completely and use only non-chlorine detergents. 6200620-00-1

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NDC 0234-0575-16

# HIBICLENS

Chlorhexidine Gluconate Solution 4% w/v

## ANTISEPTIC SKIN CLEANSER

PERSISTENT EFFECT

GREAT FOR HAND HYGIENE

GENERAL SKIN CLEANSING

**Helps reduce bacteria that potentially can cause disease**

16 fl oz (473 mL)

**Drug Facts**

**Active Ingredient**  
Chlorhexidine gluconate solution 4% w/v.....Antiseptic

**Uses**

- antimicrobial skin cleanser helps reduce bacteria that potentially can cause disease
- for skin wound and general skin cleansing
- surgical hand scrub
- healthcare personnel handwash

**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

**Drug Facts (continued)**

deafness when instilled in the middle ear through perforated eardrums.

- if contact occurs in any of these areas, rinse with cold water right away
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general 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.
- skin wound and general skin cleansing. Thoroughly rinse the area to be cleansed with water. Apply the minimum amount of the product necessary to cover the skin or wound area and wash gently. Rinse thoroughly.
- surgical hand scrub. Wet hands and forearms with water. Scrub for 3 minutes with about 5mL (4 pumps) of the product with a brush. Rinse thoroughly under running water. Repeat. Dry thoroughly.
- healthcare personnel handwash. Wet hands with water. Dispense about 5mL (4 pumps) of the product into cupped hands

**Drug Facts (continued)**

and wash in a vigorous manner for 15 seconds. Rinse and dry thoroughly.

**Other information**

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

**Inactive ingredients**  
fragrance, gluconolactone, isopropyl alcohol 4% w/v, lauramine oxide, poloxamer 237, purified water and red 40

**Questions? 1-800-843-8497**

**Mölnlycke**

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For more information go to:  
[www.hibiclens.com](http://www.hibiclens.com)  
[www.molnlycke.com](http://www.molnlycke.com)

5200773-00-1

**FPO UPC**  
**7332551065713**



NDC 0234-0575-32

# HIBICLENS<sup>®</sup>

**Chlorhexidine Gluconate  
Solution 4% w/v**

## ANTISEPTIC SKIN CLEANSER

**Helps reduce bacteria that  
potentially can cause disease**

Mölnlycke<sup>®</sup> 32 fl oz (1 qt) (946 mL)

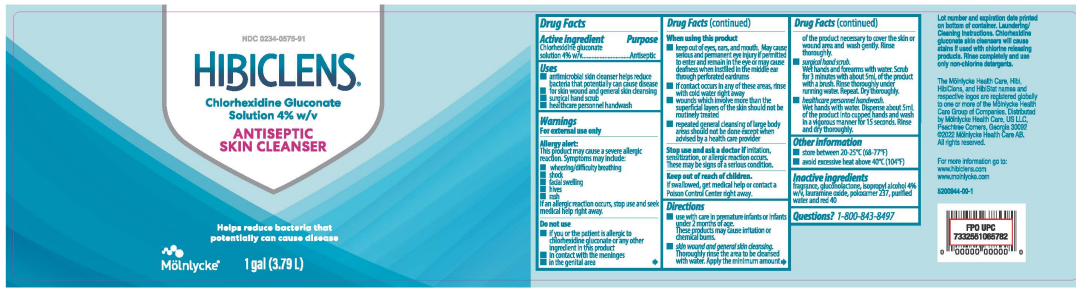
<p><b>Drug Facts</b></p> <p><b>Active Ingredient</b> Chlorhexidine gluconate solution 4% w/v</p> <p><b>Purpose</b> Antiseptic</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ antimicrobial skin cleanser helps reduce bacteria that potentially can cause disease</li> <li>■ for skin wound and general skin cleansing</li> <li>■ surgical hand scrub</li> <li>■ healthcare personnel handwash</li> </ul> <p><b>Warnings</b> For external use only</p> <p><b>Allergy alert:</b> This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> <li>■ wheezing/difficulty breathing</li> <li>■ rash</li> <li>■ facial swelling</li> <li>■ dizziness</li> <li>■ hives</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product</li> <li>■ in contact with the meninges</li> <li>■ in the genital area</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ keep out of eyes, ears, and mouth. May cause irritation and permanent eye injury if permitted to enter and remain in the eye or may cause blindness when instilled in the middle ear through perforated eardrums</li> <li>■ if contact occurs in any of these areas, rinse with cold water right away</li> <li>■ wearing which involve more than the superficial layers of the skin should not be routinely treated</li> <li>■ repeated general cleansing of large body</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p>areas should not be done except when advised by a health care provider.</p> <p><b>Stop use and ask a doctor if irritation, redness, or allergic reactions occur. These may be signs of a serious condition.</b></p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li> <li>■ skin wound and general skin cleansing: thoroughly moisten the area to be cleaned with water. Apply the minimum amount of product necessary to cover the skin or wound and then wash gently, rinse thoroughly.</li> <li>■ surgical hand scrub: wet hands and forearms with water. Scrub for 3 minutes with about 2 oz of the product with a brush. Rinse thoroughly under running water. Repeat. Dry thoroughly.</li> <li>■ healthcare personnel handwash: wet hands with water. Dispense about 2 oz of the product into spongy hands and wash in a spongy motion for 15 seconds. Rinse and dry thoroughly.</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store between 20-25°C (68-77°F)</li> <li>■ avoid excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive ingredients</b> fragrance, glycolaurate, sorbitol alcohol 45% w/v, hydrogen peroxide, polyethylene glycol, purified water and red 40</p> <p><b>Questions? 1-800-843-8497</b></p>
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Lot number and expiration date printed on bottom of container. Laundering/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products. Rinse completely and use only non-chlorine detergents.

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For more information go to:  
www.hibiclens.com  
www.molnlyckehc.com

5200960-00-1



# HIBICLENS

chlorhexidine gluconate solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0234-0575
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>POLOXAMER 237</b> (UNII: JT3U72U71K)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0234-0575-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/1976	
2	NDC:0234-0575-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/1976	
3	NDC:0234-0575-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/1976	
4	NDC:0234-0575-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/1976	
5	NDC:0234-0575-91	3790 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/1976	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017768	09/17/1976	

**Labeler** - Molnlycke Health Care (165301032)

Revised: 2/2024

Molnlycke Health Care