

HIBICLENS- chlorhexidine gluconate 4% solution
Xttrium Laboratories, Inc.

Hibiclens 4% CHG 4oz Foamer (IFP)

Active Ingredient

Chlorhexidine gluconate solution 4.0% w/v

Purpose

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 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 doctor if

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

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 5 mL (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 5 mL (4 pumps) 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

Laundering and Cleaning Instructions

Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products. Rinse completely and use only non-chlorine detergents

Principal Display Panel

NDC 0234-0575-41

Hibiclens

Chlorhexidine gluconate solution 4.0% w/v

Antiseptic Skin Cleanser

Persistent Effect

Great for Hand Hygiene

General Skin Cleansing

Helps reduce bacteria that potentially can cause disease

with foam pump Replace cap after use

4 fl oz (118mL)

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

NDC 0234-0575-41

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Drug Facts (continued)
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healthcare personnel handwash. Wet hands with water. Dispense about 5mL (4 pumps) of the product into cupped hands and wash in a vigorous manner for 15 seconds. Rinse and dry thoroughly. →

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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.molnlycke.com
5200937-00-1

Mölnlycke®

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PERSISTENT EFFECT
GREAT FOR HAND HYGIENE
GENERAL SKIN CLEANSING

Helps reduce bacteria that potentially can cause disease
With foam pump • Replace cap after use
4 fl oz (118 mL)

HIBICLENS

chlorhexidine gluconate 4% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-0575
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	213 g in 1000 mL
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Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0575-41	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017768	01/30/2024	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0575)

Revised: 1/2024

Xttrium Laboratories, Inc.