

ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate solution
Xttrium Laboratories, Inc.

DYNA-HEX 15mL

Drug Facts

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
- **patient preoperative skin preparation:** for the preparation of the patient's skin prior to surgery
- **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 meninges
- in the genital area
- as a preoperative skin preparation of the head or face

When using this product

- keep out of the 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 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 or 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 occur. 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

Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes
- dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general skin cleaning:

- 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 through 4:30 PM CST

NDC 0116-1061-15

DYNA-HEX 4 ®

(CHlorhexidine Gluconate 4% Solution)

Antiseptic

Non-Sterile SOLUTION

Contains: 4% CHlorhexidine Gluconate

Distributed by: Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY

Net Contents: 50 Single-Use 0.5 fl oz (15-mL) Packettes

4DYN15PACKLBL

NDC 0116-1061-15

DYNA-HEX 4[®]
Chlorhexidine Gluconate 4% Solution
Antiseptic
Non-Sterile Solution

Contains: 4% Chlorhexidine Gluconate
Distributed By: Xttrium Laboratories, Inc.
Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY

Net Contents: 50 Single-Use 0.5 fl oz (15-mL) Packettes



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4DY15CTNLBLB

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.

Lot number and expiration date printed on side of box

NDC 0116-1061-15

Compare to the active
ingredient in Hibiclens®*

DYNA-HEX 4[®]

Chlorhexidine Gluconate 4% Solution

Antiseptic

Non-Sterile Solution

FOR EXTERNAL USE ONLY

Dyna-Hex 4[®] reduces bacteria on the skin

Dye-Free



Distributed by
Xttrium Laboratories, Inc.
Mount Prospect, IL 60056

Net Contents: 15 mL
For Single-Use





Please refer to outer packaging for directions for use and product warnings

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

Item Code: 4DYN15PACKLBL

ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-1061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
WATER (UNII: 059QF0KO0R)	
LAURAMINE OXIDE (UNII: 4F6FC4M18W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-1061-15	15 mL in 1 CARTON; Type 0: Not a Combination Product	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	08/01/2018	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-1061)

Revised: 6/2018

Xttrium Laboratories, Inc.