

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

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**4-oz DYNA-HEX 4%**

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 ear drums.
- 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

### **Patient preoperative skin preparation:**

- apply product liberally to surgical site and swab for at least 2 minutes and 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 to 4:30 PM CST

NDC 0116-1061-04

DYNA-HEX 4 ®

(Chlorhexidine Gluconate 4% Solution)

Antiseptic

Contains: 4% Chlorhexidine Gluconate

Distributed by: Xttrium Laboratories, Inc.,

FOR EXTERNAL USE ONLY

Net Contents: 4 fl oz (118 mL)

4DY04BTLLBLH

<p>NDC 0116-1061-04</p> <p><b>DYNA-HEX 4®</b> Chlorhexidine Gluconate 4% Solution Antiseptic Non-sterile Solution</p> <p>For Single-Use Net Content: 4 fl oz (118 mL)</p>	<p><b>Drug Facts (continued)</b> <b>Warnings</b> For external use only <b>Allergy alert:</b> 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.</p>	<p><b>Drug Facts (continued)</b> ■ 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 <b>Stop use and ask a doctor if</b> irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</p>	<p><b>Drug Facts (continued)</b> rinse under running water ■ dry thoroughly <b>Healthcare personnel handwash:</b> ■ 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 <b>Patient preoperative skin preparation:</b> ■ apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel ■ repeat procedure for an additional 2 minutes and dry with a sterile towel</p>	<p>Distributed By: Xttrium Laboratories, Inc. Mount Prospect, IL 60056 4DY04BTLLBLH</p>
<p><b>Drug Facts</b> <b>Active ingredient Purpose</b> Chlorhexidine gluconate 4% ..... Antiseptic</p> <p><b>Uses</b> ■ <b>surgical hand scrub:</b> significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care ■ <b>healthcare personnel handwash:</b> helps reduce bacteria that potentially can cause disease ■ <b>patient preoperative skin preparation:</b> for the preparation of the patient's skin prior to surgery ■ <b>skin wound and general skin cleansing</b></p>	<p><b>Do not use</b> ■ 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</p> <p><b>When using this product</b> ■ 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</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> ■ use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns <b>Surgical hand scrub:</b> ■ 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</p>	<p><b>Skin wound and general skin cleaning:</b> ■ 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</p> <p><b>Other information</b> ■ store at 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F)</p> <p><b>Inactive ingredients</b> cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol</p>	<p>0 11610 61040 4</p>

## ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate solution

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>COCO DIETHANOLAMIDE</b> (UNII: 92005F972D)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>PEG-75 LANOLIN</b> (UNII: 09179OX7TB)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	
<b>TRIDECYL ALCOHOL</b> (UNII: 8I9428H868)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0116-1061-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2011	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA019125	08/31/2011	

**Labeler** - Xttrium Laboratories, Inc. (007470579)

**Registrant** - Xttrium Laboratories, Inc (007470579)

## Establishment

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