DYNA-HEX 4- chlorhexidine gluconate liquid Xttrium Laboratories, Inc.
Dyna-Hex 32oz Round & Sqaure Bottle
Active ingredient
Chlorhexidine gluconate 4% solution
Purpose
Antiseptic
Uses
<ul> <li>□ surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care</li> <li>□ healthcare personnel handwash: helps reduce bacteria that potentially can cause disease</li> </ul>
Warnings
For external use only
<b>Allergy alert:</b> This product may cause a severe allergic reaction. Symptoms may include:
<ul> <li>□ wheezing/difficulty breathing</li> <li>□ shock</li> <li>□ facial swelling</li> <li>□ hives</li> <li>□ rash</li> </ul>
If an allergic reaction occurs, stop use and seek medical help right away.
<ul> <li>Do not use</li> <li>if you or the patient are allergic to chlorhexidine gluconate or any other ingredient in this product</li> </ul>
When using this product
<ul> <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 solution should contact these areas, rinse out promptly and thoroughly with water</li> <li>wounds which involve more than the superficial layers of the skin should not be routinely treated</li> </ul>

#### 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 2.0 cubic inches 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
scrub for an additional 3 minutes with 2.0 cubic inches of product and rinse under
running water
dry thoroughly
Healthcare personnel handwash:
wet hands with water
$\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $
☐ rinse and dry thoroughly

#### Other Information

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

cocamide DEA, fragrance, glucono-delta-lactone, 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

**To Install:** Remove bottle cap and apply dispensing cap. Slide dispenser into bracket, inserting the open air inlet onto proper receptacle

Container is single use only. Discard when empty.

### 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.

#### **Principle Display Panel**

NDC 0116-1060-32

DYNA-HEX 4®

Chlorhexidine Gluconate 4% Solution

**Antiseptic** 

Contains: 4% Chlorhexidine Gluconate

Distributed By: Xttrium Laboratories, Inc. Mount Prospect, IL 60056

CHLORHEXIDINE GLUCONATE

Net Contents: 32 fl oz (1 qt) (946 mL)

4DYN32RNDLBL



NDC 0116-1060-33

DYNA-HEX 4®

Chlorhexidine Gluconate 4% Solution

**Antiseptic** 

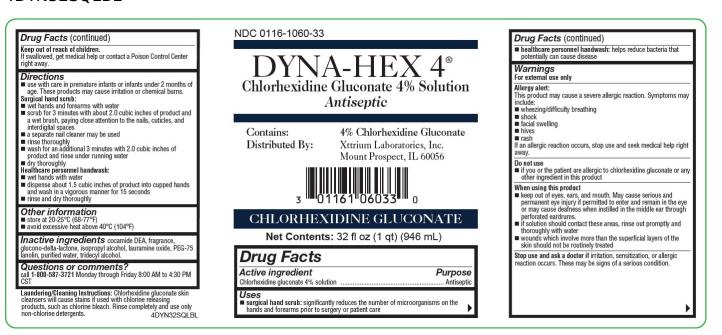
Contains: 4% Chlorhexidine Gluconate

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CHLORHEXIDINE GLUCONATE

Net Contents: 32 fl oz (1 qt) (946 mL)

4DYN32SQLBL



#### chlorhexidine gluconate liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0116-1060

**Route of Administration** TOPICAL

# Active Ingredient/Active Moiety Ingredient Name CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII: R4KO0DY52L) Basis of Strength CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - GLUCONATE in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
PEG-75 LANOLIN (UNII: 091790X7TB)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
GLUCONOLACTONE (UNII: WQ29KQ9POT)			
WATER (UNII: 059QF0KO0R)			
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)			
TRIDECYL ALCOHOL (UNII: 819428H868)			
COCO DIETHANOLAMIDE (UNII: 92005F972D)			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0116- 1060-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/15/2023		
2	NDC:0116- 1060-33	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/14/2023		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
NDA	NDA019127	11/15/2023				

# Labeler - Xttrium Laboratories, Inc. (007470579)

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

Establishment					
Name	Address	ID/FEI	Business Operations		
Xttrium Laboratories, Inc.		007470579	manufacture(0116-1060)		

Revised: 12/2023 Xttrium Laboratories, Inc.