# DYNA-HEX 4- chlorhexidine gluconate liquid Xttrium Laboratories, Inc.

-----

4% Dyna-Hex, 18-oz

#### **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
- 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 are allergic to chlorhexidine gluconate or any other ingredient in this product

## When using this product

- keep out of 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
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

## 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 3 full pumps (5 grams) of product and a wet brush paying close attention to the nails, cuticles, and interdigital spaces
- a seperate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 3 full pumps (5 grams) of product and rinse under running water
- dry thoroughly

#### **Healthcare personnel handwash:**

- wet hands with water
- dispense 3 full pumps (5 grams) of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

## Skin wound and general skin cleansing:

☐ thoroughly rinse the area to be cleaned with water
$\square$ 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, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

#### Questions of Comments?

Call **1-800-587-3721** Monday through Friday 8:00 AM to 4:30 PM CST

## Laundering/Cleaning Instructions

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.

## Package/Label Principal Display Panel

NDC 0116-1060-18

DYNA-HEX 4®

Chlorhexidine Gluconate 4% Solution

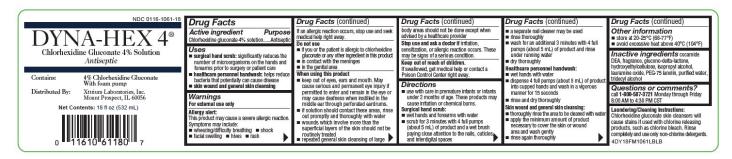
Antiseptic

Contains: 4% Chlorhexidine Gluconate With foam pump

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

Net Contents: 18 fl oz (532 mL)

4DYN18BTLLBLB



#### **DYNA-HEX 4**

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	<b>Basis of Strength</b>	Strength
	CHLORHEXIDINE GLUCONATE	4 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)			
PEG-75 LANOLIN (UNII: 091790X7TB)			
WATER (UNII: 0590F0KO0R)			

TRIDECYL ALCOHOL (UNII: 819428H868)

COCO DIETHANOLAMIDE (UNII: 92005F972D)

GLUCONOLACTONE (UNII: WQ29KQ9POT)

HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116- 1060-18	535 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA019125	01/01/2016		

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

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

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

Revised: 11/2023 Xttrium Laboratories, Inc.