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

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Dyna-Hex 4: 4oz FM, 8oz, 16oz, 18oz, 32oz, 1 Gallon

# **Active Ingredient**

Chlorhexidine gluconate

# **Drug Facts**

### **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 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 (only in 4-oz)

# 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 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.

### Do not use

- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
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- in the genital area

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# Stop use and ask 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.

### Direction

• use with care in premature infants and 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

### 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

# Package label and principal display panel

NDC 0116-1061-08

DYNA-HEX 4 ®

(Chlorhexidine Gluconate 4% Solution)

Antiseptic

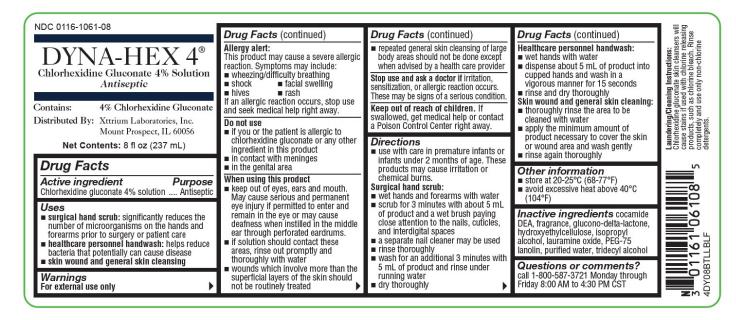
Contains: 4% Chlorhexidine Gluconate

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

### FOR EXTERNAL USE ONLY

Net Contents: 8 fl oz (237 mL)

### 4DY08BTLLBLF



NDC 0116-1061-16

DYNA-HEX 4 ®

(Chlorhexidine Gluconate 4% Solution)

Antiseptic

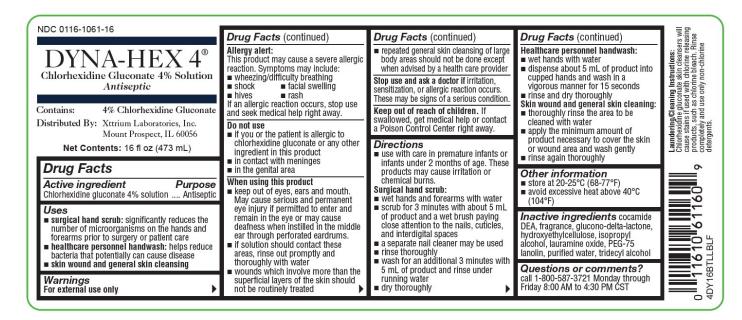
Contains: 4% Chlorhexidine Gluconate

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

FOR EXTERNAL USE ONLY

Net Contents: 16 fl oz (473 mL)

4DY16BTLLBLF



NDC 0116-1061-32

DYNA-HEX 4 ®

(Chlorhexidine Gluconate 4% Solution)

Antiseptic

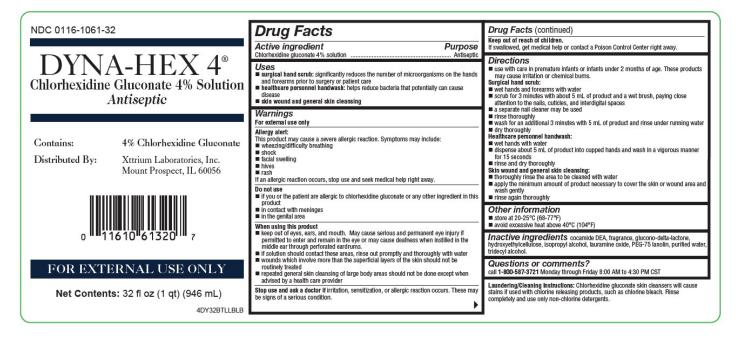
Contains: 4% Chlorhexidine Gluconate

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

FOR EXTERNAL USE ONLY

Net Contents: 32 fl oz (946 mL)

4DY32BTLLBLB



DYNA-HEX 4 ®

(Chlorhexidine Gluconate 4% Solution)

**Antiseptic** 

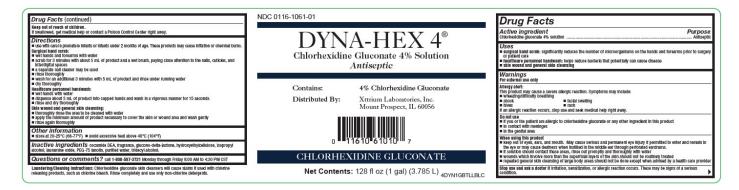
Contains: 4% Chlorhexidine Gluconate

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

FOR EXTERNAL USE ONLY

Net Contents: 128 fl oz (1 gal)

4DYN1GBTLLBLC



NDC 0116-1061-40

DYNA-HEX 4®

Chlorhexidine Gluconate 4% Solution

Antiseptic

Contains:

4% Chlorhexidine Gluconate With foam pump

Distributed By:

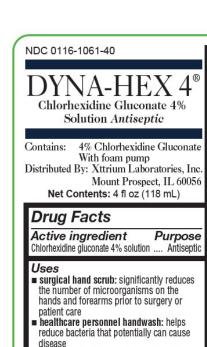
Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY

Net Contents: 4 fl oz (118mL)

4DY04FM1061LBLB



### Drug Facts (continued)

#### Allergy alert:

This product may cause a severe allergic reaction. Symptoms may

- 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

#### 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 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

#### Drug Facts (continued)

done except when advised by a healthcare 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 4 full pumps (6 grams) 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 4 full pumps (6 grams) of product and rinse under running water
- dry thoroughly

#### Drug Facts (continued)

#### Healthcare personnel handwash: wet hands with water

- dispense 4 full pumps (6 grams) of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly 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 aently
- rinse again thoroughly

### Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat abové 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



Laundering/Cleaning Instructions:
Chlorhexidine glucornate skin cleansers will cause
stains if used with chlorine releasing products, such
as chlorine bleach. Rinse completely and use only
non-chlorine detergents.

NDC 0116-1061-18

skin wound and general skin cleansing

DYNA-HEX 4®

Warnings

For external use only

Chlorhexidine Gluconate 4% Solution

Antiseptic

Contains:

4% Chlorhexidine Gluconate

Distributed By:

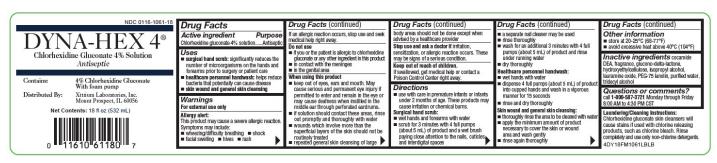
Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY

Net Contents: 18 fl oz (532mL)

4DY18FM1061LBLB



# chlorhexidine gluconate solution

<b>Product</b>	Inform	ation
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**Route of Administration** TOPICAL

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

Inactive Ingredients			
Ingredient Name	Strength		
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)			
WATER (UNII: 059QF0KO0R)			
TRIDECYL ALCOHOL (UNII: 819428H868)			
GLUCONOLACTONE (UNII: WQ29KQ9POT)			
PEG-75 LANOLIN (UNII: 091790X7TB)			
COCO DIETHANOLAMIDE (UNII: 92005F972D)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116- 1061-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2011	
2	NDC:0116- 1061-16	437 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2011	
3	NDC:0116- 1061-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2011	
4	NDC:0116- 1061-01	15142 mL in 1 JUG; Type 0: Not a Combination Product	08/31/2011	
5	NDC:0116- 1061-40	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	
6	NDC:0116- 1061-18	532 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2011	

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

# Registrant - Xttrium Laboratories, Inc. (007470579)

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

Revised: 12/2023 Xttrium Laboratories, Inc.