DYNA-HEX 2- chlorhexidine gluconate liquid Xttrium Laboratories, Inc.

Dyna-Hex 2

Drug Facts

Active ingredient

chlorhexidine gluconate 2% 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 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 that 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.

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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 under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.

scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers

rinse thoroughly under running water for 30 seconds

wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds

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

Other information

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

Inactive ingredients

citric add. cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?

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

DYNA-HEX 2®

NDC 0116-1021-08

Chlorhexidine Gluconate 2% Solution

Antiseptic Foam Handwash

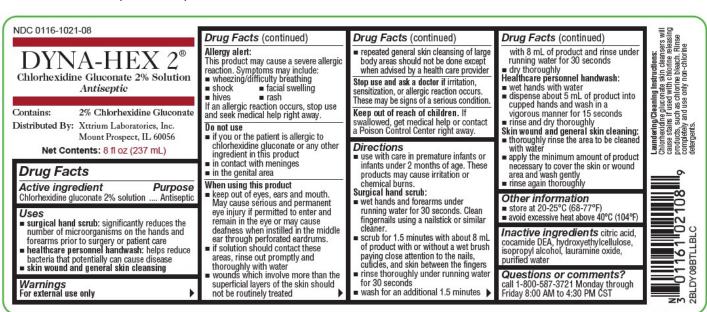
Distributed by:

Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

2BLDY08BTLLBLC

Net Wt 8 fl oz (237 mL)



Chlorhexidine Gluconate 2% Solution

Antiseptic

Contains: 2% Chlorhxidine Gluconate

FOR EXTERNAL USE ONLY

FDA approved formula

Helps Reduce Bacteria

Fragrance-Free

Used by Healthcare personnel in hospitals

Net Contents: 8.5 fl oz (251 mL)

2DYN85FLBL





- 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 initation, 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 awa

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 under running water for 30 seconds. Clean fingernails
- using a nailstick or similar cleaner.

 scrub for 1.5 minutes with about 8 mL of product (5 full pumps) with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers.
- in inse thoroughly under running water for 30 seconds

 wash for an additional 1.5 minutes with 8 mL of product (5 full pumps) and rins under running water for 30 seconds ■ dry thoroughly

Drug Facts (continued)

Healthcare personnel handwash:

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

Other information

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

Inactive ingredients

citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide,

Questions or comments? call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

Laundering/Cleaning Instructions:

Chlorhexidine gluconale skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

NDC 0116-1021-16

Dyna-Hex 2 ®

Chlorhexidine Gluconate 2% Solution

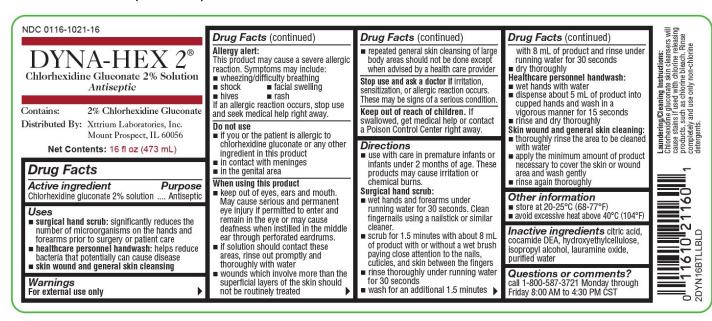
Antiseptic Foam Handwash

Distributed by:

Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

2DYN16BTLLBLD



NDC 0116-1021-17

Dyna-Hex 2®

Chlorhexidine Gluconate 2% Solution

Antiseptic Foam Handwash

Distributed by:

Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

2BLDYNATLBLD

Net Wt 16 fl oz (473 mL)

DYNA-HEX 2® Chlorhexidine Gluconate 2% Solution Antiseptic

Contains: 2% Chlorhexidine Gluconate

Distributed By: Xttrium Laboratories, Inc.

Mount Prospect, IL 60056



FOR EXTERNAL USE ONLY

Net Contents: 16 fl oz (473 mL)

Drug Facts

Active ingredient

Purpose

Chlorhexidine gluconate 2% solution

..... 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.

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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 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 under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- 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 cleansing:

- 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 citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?

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

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.

NDC 0116-1021-32

Dyna-Hex 2®

Chlorhexidine Gluconate 2% Solution

Antiseptic Foam Handwash

Distributed by:

Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

2DYN32BTLLBLA

Net Wt 32 fl oz (946 mL)

DYNA-HEX 2® Chlorhexidine Gluconate 2% Solution Antiseptic

Contains: 2% Chlorhexidine Gluconate

Distributed By: Xttrium Laboratories, Inc.

Mount Prospect, IL 60056



FOR EXTERNAL USE ONLY

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

2DYN32BTLLBLA

Drug Facts

Active ingredient

Chlorhexidine gluconate 2% 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 or the patient are 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
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Directions

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Surgical hand scrub:

- wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- 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 citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?

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

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.

NDC 0116-1021-01

Dyna-Hex 2®

Chlorhexidine Gluconate 2% Solution

Antiseptic Foam Handwash

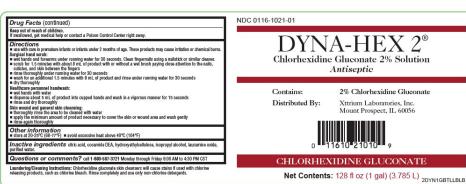
Distributed by:

Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

2DYN1GBTLLBLB

Net Wt 128 fl oz (1 gal)



Drug Facts

Active ingraction:

Charteedras glucomate 2% solution

Antiseptic

Uses

In agreed has deserts significantly reduces the number of microorganisms on the hands and forearms prior to surgesty or plates to a significant period by the produce solution in the product or plates or a significant general sale desents great plates or plates or a significant general sale desents great plates or plates or a significant general sale desents great great

DYNA-HEX 2

chlorhexidine gluconate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-1021
Route of Administration	TOPICAL		

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
		CHLORHEXIDINE GLUCONATE	2 g in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
COCO DIETHANOLAMIDE (UNII: 92005F972D)			
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZ N16)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)			
WATER (UNII: 059QF0KO0R)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0116- 1021-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2014		
2	NDC:0116- 1021-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2014		
3	NDC:0116- 1021-17	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2014		
4	NDC:0116- 1021-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2014		
5	NDC:0116- 1021-01	15142 mL in 1 JUG; Type 0: Not a Combination Product	01/01/2014		
6	NDC:0116- 1021-85	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA019422	01/01/2014		

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment					
Name	Address	ID/FEI	Business Operations		
Xttrium Laboratories, Inc.		007470579	manufacture(0116-1021)		

Revised: 12/2023 Xttrium Laboratories, Inc.