

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

Dyna-Hex 32oz Round & Sqaure Bottle

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

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

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

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

□ dispense about 1.5 cubic inches of product 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)

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

<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. Surgical hand scrub: <ul style="list-style-type: none"> 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 rise thoroughly scrub for an additional 3 minutes with 2.0 cubic inches of product and rise under running water dry thoroughly Healthcare personnel handwash: <ul style="list-style-type: none"> wet hands with water dispense about 1.5 cubic inches of product into cupped hands and wash in a vigorous manner for 15 seconds rinse and dry thoroughly <p>Other information</p> <ul style="list-style-type: none"> store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F) <p>Inactive ingredients: cocamide DEA, fragrance, glucono-delta-lactone, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, triethyl alcohol.</p> <p>Questions or comments? call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST</p> <p>To install: Remove bottle cap and apply dispensing cap. Slide dispenser into bracket, inserting the open air inlet onto proper nozzle.</p> <p>Container is single use only. Discard when empty.</p> <p>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.</p>	<p>NDC 0116-1060-32</p> <p>DYNA-HEX 4® Chlorhexidine Gluconate 4% Solution Antiseptic</p> <hr/> <p>Contains: 4% Chlorhexidine Gluconate Distributed By: Xttrium Laboratories, Inc. Mount Prospect, IL 60056</p>  <p>3 01161 06032 3</p> <p>CHLORHEXIDINE GLUCONATE</p> <p>Net Contents: 32 fl oz (1 qt) (946 mL) 4DYN32RNDLBL</p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Chlorhexidine gluconate 4% solution</td> <td>Antiseptic</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> 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 <p>Warnings For external use only</p> <p>Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> wheezing/difficulty breathing shock facial swelling hives rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> if you or the patient are allergic to chlorhexidine gluconate or any other ingredient in this product <p>When using this product</p> <ul style="list-style-type: none"> 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 <p>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</p>	Active ingredient	Purpose	Chlorhexidine gluconate 4% solution	Antiseptic
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NDC 0116-1060-33

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Chlorhexidine Gluconate 4% Solution

Antiseptic


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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	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PEG-75 LANOLIN (UNII: 09179OX7TB)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
WATER (UNII: 059QF0KO0R)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
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)

