

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 separate 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
- 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

<p>NDC 0116-1061-18</p> <p>DYNA-HEX 4®</p> <p>Chlorhexidine Gluconate 4% Solution</p> <p>Antiseptic</p> <p>Contains: 4% Chlorhexidine Gluconate With foam pump</p> <p>Distributed By: Xttrium Laboratories, Inc. Mount Prospect, IL 60056</p> <p>Net Contents: 18 fl oz (532 mL)</p> 	<p>Drug Facts</p> <p>Active ingredient Chlorhexidine gluconate 4% solution.....Antiseptic</p> <p>Purpose</p> <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 skin wound and general skin cleansing <p>Warnings</p> <p>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>Drug Facts (continued)</p> <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 is allergic to chlorhexidine gluconate or any other ingredient in this product in contact with the meninges in the genital area <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 repeated general skin cleansing of large 	<p>Drug Facts (continued)</p> <p>body areas should not be done except when advised by a healthcare provider</p> <p>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</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. <p>Surgical hand scrub:</p> <ul style="list-style-type: none"> wet hands and forearms with water scrub for 3 minutes with 4 full pumps (about 5 mL) of product and a wet brush paying close attention to the nails, cuticles and interdigital spaces 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> a separate nail cleaner may be used rinse thoroughly wash for an additional 3 minutes with 4 full pumps (about 5 mL) of product and rinse under running water dry thoroughly <p>Healthcare personnel handwash:</p> <ul style="list-style-type: none"> wet hands with water dispense 4 full pumps (about 5 mL) of product into cupped hands and wash in a vigorous manner for 15 seconds rinse and dry thoroughly <p>Skin wound and general skin cleansing:</p> <ul style="list-style-type: none"> 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 	<p>Drug Facts (continued)</p> <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, hydroxyethylcellulose, 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>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>4DY18FM1061LBLB</p>
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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	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M41630Z)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
WATER (UNII: 059QF0KO0R)	

TRIDECYL ALCOHOL (UNII: 8I9428H868)	
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	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-1060)

Revised: 11/2023

Xttrium Laboratories, Inc.