

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

4-oz DYNA-HEX 4%

Drug Facts

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
- **patient preoperative skin preparation:** for the preparation of the patient's skin prior to surgery
- **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

When using this product

- keep out of the 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 ear drums.
- 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 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

Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

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

NDC 0116-1061-04

DYNA-HEX 4 ®

(Chlorhexidine Gluconate 4% Solution)

Antiseptic

Contains: 4% Chlorhexidine Gluconate

Distributed by: Xttrium Laboratories, Inc.,

FOR EXTERNAL USE ONLY

Net Contents: 4 fl oz (118 mL)

4DY04BTLLBLH

<p>NDC 0116-1061-04</p> <p>DYNA-HEX 4® Chlorhexidine Gluconate 4% Solution Antiseptic Non-sterile Solution</p> <p>For Single-Use Net Content: 4 fl oz (118 mL)</p>	<p>Drug Facts (continued)</p> <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>Drug Facts (continued)</p> <ul style="list-style-type: none">■ 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 <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>Drug Facts (continued)</p> <p>rinse under running water ■ dry thoroughly</p> <p>Healthcare personnel handwash:</p> <ul style="list-style-type: none">■ 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 <p>Patient preoperative skin preparation:</p> <ul style="list-style-type: none">■ apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel■ repeat procedure for an additional 2 minutes and dry with a sterile towel <p>Skin wound and general skin cleaning:</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>Distributed By: Xttrium Laboratories, Inc. Mount Prospect, IL 60056</p> <p>4DY04BTLLBLH</p>  <p>0 11610 61040 4</p>			
<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Chlorhexidine gluconate 4%</td><td>Antiseptic</td></tr></tbody></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■ patient preoperative skin preparation: for the preparation of the patient's skin prior to surgery■ skin wound and general skin cleansing	Active ingredient	Purpose	Chlorhexidine gluconate 4%	Antiseptic	<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 meninges■ in the genital area■ as a preoperative skin preparation of the head or face <p>When using this product</p> <ul style="list-style-type: none">■ keep out of the 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	<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 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	<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, tridecyl alcohol</p>
Active ingredient	Purpose						
Chlorhexidine gluconate 4%	Antiseptic						

ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-1061
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
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
WATER (UNII: 059QF0KO0R)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-1061-04	118 mL in 1 BOTTLE, PLASTIC; 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	

Labeler - Xttrium Laboratories, Inc. (007470579)

Revised: 4/2025

Xttrium Laboratories, Inc.