

ANTISEPTIC SKIN CLEANSER EXIDINE-2 CHG- chlorhexidine gluconate solution
Xttrium Laboratories, Inc.

Quality Choice 2%

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

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 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 about 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, purified water

Questions or comments?

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

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

Warning: This product can expose you too coconut oil diethanolamine condensate (cocamide diethanolamine), whichs is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov

Package Label

NDC 63868-280-02

Chlorhexidine Gluconate 2% Solution

Antiseptic

Distributed by:

C,D,M,A,Inc.

Novi, MI 48376 USA

qualitychoice.com

2QC02BTLLBLB

Quality Choice ®

Net Wt 2 fl oz (60 mL)

NDC 63868-280-02



Antiseptic Skin Cleanser

Antiseptic/Antimicrobial Skin Cleanser

Chlorhexidine Gluconate 2% Solution
Reduces Bacteria on the Skin

FOR EXTERNAL USE ONLY
TRICLOSAN FREE
FDA APPROVED

2 fl oz (60 mL) BOTTLE

20C02BTL1LB
Manufactured by: CDM, LLC, Ph.D.
4557 W. 9 Mile Rd
Novi, MI 48275
www.qualitychoice.com
Questions: 248-413-3700



35515199557 4



NDC 63868-280-02



Antiseptic Skin Cleanser

Antiseptic/Antimicrobial Skin Cleanser

Chlorhexidine Gluconate 2% Solution
Reduces Bacteria on the Skin

FOR EXTERNAL USE ONLY
TRICLOSAN FREE
FDA APPROVED

2 fl oz (60 mL) BOTTLE

Drug Facts

Active ingredient

Chlorhexidine gluconate

2% solution Antiseptic

Purpose

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



Drug Facts (continued)

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 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



Drug Facts (continued)

- 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 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



Drug Facts (continued)

- 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 about 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, purified water.

Questions or comments? call 1-800-935-2362
Monday through Friday 9:00 AM to 4:00 PM EST

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.



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NDC 63868-280-08

QUALITY CHOICE

Antiseptic Skin Cleanser

Antiseptic/Antimicrobial Skin Cleaner

Chlorhexidine Gluconate 2% Solution

Reduces Bacteria on the Skin

FOR EXTERNAL USE ONLY

TRICLOSAN FREE

FDA APPROVED

8.5 fl oz (250 mL)

2QC85BTLLBLFB

NDC 63968-280-08



Antiseptic Skin Cleanser

Antiseptic/Antimicrobial Skin Cleanser

Chlorhexidine Gluconate 2% Solution
Reduces Bacteria on the Skin

FOR EXTERNAL USE ONLY
TRICLOSAN FREE
FDA APPROVED

8.5 fl oz (250 mL)

20C85BTLBLFB

WARNING: This product can expose you to coconut oil diethanolamine condensate (cocamide diethanolamine), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.



Distributed by C.D.M.A., Inc.
4357 W 9 Mile Rd
New, MI 48375
www.qualitychoice.com
Questions: 800-993-2352
20C85BTLBLBD



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

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
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Do not use

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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

Drug Facts (continued)

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 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.
- rinse thoroughly under running water for 30 seconds

Drug Facts (continued)

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

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, purified water

Questions or comments? call 1-800-935-2362

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Laundering/Cleaning Instructions:

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ANTISEPTIC SKIN CLEANSER EXIDINE-2 CHG

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-2800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	2 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LAURAMINE OXIDE (UNII: 4F6FC4M18W)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
WATER (UNII: 059QF0K00R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-2800-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2016	02/29/2020
2	NDC:0116-2800-08	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019422	07/01/2016	

Labeler - Xttrium Laboratories, Inc. (007470579)**Registrant** - Xttrium Laboratories, Inc. (007470579)**Establishment**

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-2800)