

**BACTOSHIELD CHG- chlorhexidine gluconate solution**  
Xttrium Laboratories, Inc.

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**Bactoshield<sup>®</sup> CHG 2%**

**Chlorhexidine Gluconate 2% Solution**

***Drug Facts***

**Active ingredient**

chlorhexidine gluconate 2% solution

**Purposes**

surgical hand scrub  
healthcare personnel handwash  
patient preoperative skin preparation  
skin wound and general skin cleansing

**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:** 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 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
- 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 the 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

### **Patient preoperative skin preparation:**

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

### **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 1-800-548-4873 Monday through Friday 8:00 AM to 4:30 PM CST

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

Bactoshield® CHG 2%

NDC 11084-814-03

Surgical Scrub

Chlorhexidine Gluconate 2% Solution Antiseptic

Non-sterile Solution

Surgical Scrub

2% CHG

Antimicrobial

For Single-Use

Net Contents: 118 mL (4 fl oz)

1322-52G(319)

REORDER #1322-39

61345

2BACT04BTLLBLE





Manufactured for: Deb USA Inc.  
 Charlotte, NC 28217 ■ 1-866-783-0422  
 www.debmed.com  
 Product Made in U.S.A.

## ***Drug Facts***

### ***Active ingredient***

Chlorhexidine gluconate

2% solution ..... surgical hand scrub

healthcare personnel handwash

patient preoperative skin preparation

skin wound and general skin cleansing

### ***Purposes***

Lift Here



## **Drug Facts** (continued)

### **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:** 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 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
- 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



**Drug Facts** (continued)

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

**Patient preoperative skin preparation:** ■ apply product liberally to surgical site and swab for at least 2 minutes ■ dry with a sterile towel ■ repeat procedure for an additional 2 minutes and dry with a sterile towel

**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°)  
■ 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 1-866-783-0422  
Monday through Friday 8:00 AM to 4:30 PM EST



**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](http://www.P65Warnings.ca.gov).

Bactoshield® CHG 2%

NDC 11084-814-24

Surgical Scrub

2% Solution Antiseptic

Chlorhexidine Gluconate

Surgical Scrub

2% CHG

Antimicrobial

Net Contents: 32 fl oz (946 mL)

REORDER #1322-24

61335

1322-21J(319)

2BACT32BTLLBLJ

<p><b>Drug Facts (continued)</b></p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li> </ul> <p><b>Surgical hand scrub:</b></p> <ul style="list-style-type: none"> <li>wet hands and forearms with water</li> <li>scrub for 3 minutes with about 5 mL of product and a wet brush, paying close attention to the nails, cuticles, and interdigital spaces</li> <li>a separate nail cleaner may be used</li> <li>rinse thoroughly</li> <li>wash for an additional 3 minutes with 5 mL of product and rinse under running water</li> <li>dry thoroughly</li> </ul> <p><b>Healthcare personnel handwash:</b></p> <ul style="list-style-type: none"> <li>wet hands with water</li> <li>dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds</li> <li>rinse and dry thoroughly</li> </ul> <p><b>Skin wound and general skin cleansing:</b></p> <ul style="list-style-type: none"> <li>thoroughly rinse the area to be cleaned with water</li> <li>apply the minimum amount of product necessary to cover the skin or wound area and wash gently</li> <li>rinse again thoroughly</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 20-25°C (68-77°F)</li> <li>avoid excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive ingredients</b> citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water.</p> <p><b>Questions or comments?</b> call 1-866-783-0422 Monday through Friday 8:00 AM to 4:30 PM EST</p>	<p><b>Bactoshield®</b> <b>CHG 2%</b></p> <p>NDC 11084-814-24</p> <p><b>Surgical Scrub</b> 2% Solution Antiseptic Chlorhexidine Gluconate</p> <p> Surgical Scrub</p> <p> 2% CHG</p> <p> Antimicrobial</p> <p>Net Contents: 32 fl oz (946 mL)</p> <p>REORDER # <b>1322-24</b></p> <p>61335 1322-21J(319) 2BACT32BTLBLJ</p> 	<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Chlorhexidine gluconate 2% solution</p> <p><b>Purposes</b> surgical hand scrub healthcare personnel handwash skin wound and general skin cleansing</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>surgical hand scrub significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care</li> <li>healthcare personnel handwash helps reduce bacteria that potentially can cause disease</li> <li>skin wound and general skin cleansing</li> </ul> <p><b>Warnings</b></p> <p>For external use only</p> <p><b>Allergy alert:</b> This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> <li>wheezing/difficulty breathing</li> <li>shock</li> <li>facial swelling</li> <li>hives</li> <li>rash</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product</li> <li>in contact with meningitis</li> <li>in the genital area</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>if solution should contact these areas, rinse out promptly and thoroughly with water</li> <li>wounds which involve more than the superficial layers of the skin should not be routinely treated</li> <li>repeated general skin cleansing of large body areas should not be done except when advised by a health care provider</li> </ul> <p>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</p>
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Bactoshield® CHG 2%

NDC 11084-814-08

Surgical Scrub

Chlorhexidine Gluconate 2% Solution Antiseptic

Surgical Scrub

2% CHG

Antimicrobial

Net Contents: 128 fl oz (1Gal)(3.78 Liters)

1322-06G(319)

REORDER #1322-08

62662

2BACT1GLBLB

Bactoshield®  
CHG 2%

debmed

NDC 11094-814-08

# Surgical Scrub

Chlorhexidine Gluconate  
2% Solution Antiseptic



Surgical Scrub



2% CHG



Antimicrobial

Net Contents: 128 Fl Oz (1 Gall) (3.78 Liters)



1122-060 (919)

6 91240 06198 4

monomer A  
1322-48

62662  
2BACT16LMB

## Drug Facts

### Active Ingredient

Chlorhexidine gluconate  
2% solution

### Purpose(s)

..... surgical hand scrub  
healthcare personnel handwash  
skin wound and general skin cleansing

### Uses

- surgical hand scrubs: 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

## Drug Facts (continued)

### 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 meningitis
- 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 scrubs:

- 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



<p><b>Drug Facts (continued)</b></p> <p><b>Healthcare personnel handwash:</b></p> <ul style="list-style-type: none"> <li>• wet hands with water</li> <li>• dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds</li> <li>• rinse and dry thoroughly</li> </ul> <p><b>Skin wound and general skin cleansing:</b></p> <ul style="list-style-type: none"> <li>• thoroughly rinse the area to be cleaned with water</li> <li>• apply the minimum amount of product necessary to cover the skin or wound area and wash gently</li> <li>• rinse again thoroughly</li> </ul> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>• store at 20-25°C (68-77°F)</li> <li>• avoid excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive Ingredients:</b> citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water.</p> <p><b>Questions or comments?</b> call 1-866-783-0422 Monday through Friday 8:00 AM to 4:30 PM EST</p>
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 **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](http://www.P65Warnings.ca.gov).

Manufactured for: Deb USA Inc.  
Charlotte, NC 28217  
1-866-783-0422  
[www.debmed.com](http://www.debmed.com)

Product Made in U.S.A.

NDC 11084-814-41

Bactoshield CHG 2%

Chlorhexidine Gluconate 2% Solution

Antiseptic

Healthcare Personnel Handwash

REORDER #: 1322-87

Manufactured for:

Deb USA, Inc.

Charlotte, NC 28217

1-866-783-0422

[www.debmed.com](http://www.debmed.com)

Contents: 33.8 fl oz (1.05 qt) (1 Liter)

61707

1322-86K (319)

SDSNATBKLBLA

NDC 11084-814-41

Bactoshield CHG 2%  
Chlorhexidine Gluconate 2% Solution  
Antiseptic  
Healthcare Personnel Handwash  
REORDER #: 1322-87

Manufactured for:  
Deb USA, Inc.  
Charlotte, NC 28217  
1-866-783-0422  
www.debmed.com



Contents: 33.8 fl oz (1.05 qt) (1 Liter)



61707 1322-86K (319)  
SDSNATBNLBLA

### 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

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 cause deafness ▶

### Drug Facts (continued)

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 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 ▶

**Drug Facts (continued)**

**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

**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 1-866-783-0422 Monday through Friday 8:00 AM to 4:30 PM EST



**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](http://www.P65Warnings.ca.gov).

NDC 11084-814-41

SDSNATFTLBLE

NDC 11084-814-41

**Bactoshield®**  
CHG 2%

Chlorhexidine Gluconate  
2% Solution Antiseptic

**debmed**

REORDER# 1322-87

SDSNATFTLBLE

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Chlorhexidine gluconate 2% solution	Antiseptic
<b>Uses</b> • 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	
<b>Warnings</b>	
For external use only	
<b>Allergy Alert</b> 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 • 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.	
<b>Directions</b> • use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. <b>Surgical hand scrub:</b> • 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 <b>Healthcare personnel handwash:</b> • 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	
<b>Other information</b> • store at 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water	

**WARNING:** Cancer [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

Net Contents: 33.8 fl oz (1.05 qt) (1 liter)

**BACTOSHIELD CHG**

chlorhexidine gluconate solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0116-1322
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE OXIDE (UNII: 4F6FC4M18W)	
WATER (UNII: 059QF0K00R)	

**Product Characteristics**

<b>Color</b>	yellow (Clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-1322-08	3708 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/1999	
2	NDC:0116-1322-24	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/1999	
3	NDC:0116-1322-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/1999	
4	NDC:0116-1322-41	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/04/1999	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA019422	10/04/1999	

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

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-1322)

Revised: 11/2019

Xttrium Laboratories, Inc.