

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

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**Bactoshield CHG<sup>®</sup> 4%**

**Chlorhexidine Gluconate Solution**

***Drug Facts***

**Active ingredient**

chlorhexidine gluconate 4% 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 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
- 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)
- void 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 **1-800-548-4873** 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 4%

NDC 11084-815-03

Surgical Scrub

Chlorhexidine Gluconate 4% Solution Antiseptic

Non-sterile Solution

Surgical Scrub

4% CHG

Antimicrobial

For Single-Use

Net Contents: 118 mL (4 fl oz)

REORDER #1344-39

1344-52F(319)

61346

4BACT04BTLLBLD



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.

## Drug Facts

### Active ingredient

Chlorhexidine gluconate

4% 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**

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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 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
- 

**Drug Facts (continued)**

- 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
- 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** cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

**Questions or comments?** call 1-866-783-0422  
Monday through Friday 8:00 AM to 4:30 PM EST



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Bactoshield ® CHG 4%

NDC 11084-815-34

Surgical Scrub

Chlorhexidine Gluconate 4% Solution Antiseptic

Surgical Scrub

4% CHG

Antimicrobial

Net Contents: 473mL (16 fl oz) (1 pt)

REORDER #1344-33

61340

1344-31H(319)

4BACT16BTLLBLE

Bactoshield®  
CHG 4%

debmed

NDC 1344-31H-34

## Surgical Scrub

Chlorhexidine Gluconate 4% Solution Antiseptic



Surgical Scrub



4% CHG



Antimicrobial

WHD FORM #  
1344-33

Net Contents: 473mL (16 fl oz) (1 pt)



61340  
1344-31H(319)  
4BACT16TLL9LE

### Drug Facts

#### Active ingredient

Chlorhexidine gluconate 4% solution ..... surgical hand scrub  
healthcare personnel handwash  
skin wound and general skin cleansing

#### Purposes

#### 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.

▲ Lift Here

### **Drug Facts (continued)**

#### **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

#### **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 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

#### **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** cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol



### Drug Facts (continued)

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Product Made in U.S.A.

Bactoshield® CHG 4%

NDC 11084-815-24

Surgical Scrub

4% Solution Antiseptic Chlorhexidine Gluconate

Surgical Scrub

4% CHG

Antimicrobial

Net Contents: 32 fl oz (946 mL)

REORDER #1344-24

61341

1344-21H(319)

4BACT32BTLLBLB

### Drug Facts (continued)

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

#### 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, hydroxyethylulose, isopropyl alcohol, butamine oxide, PEG-75 lanolin, purified water, triethyl alcohol.

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Product Made in U.S.A.

Bactoshield®  
CHG 4%

debmed

NDC 11084-815-24

**Surgical Scrub**

4% Solution Antiseptic  
Chlorhexidine Gluconate



Surgical Scrub



4% CHG



Antimicrobial

REORDER #  
1344-24

Net Contents: 32 fl oz (946 mL)

61341  
1344-21H(319)  
4BACT32BTLLBLB



### Drug Facts

#### Active ingredient

Chlorhexidine gluconate 4% solution

#### Purposes

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

#### Warnings

For external use only

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- facial swelling
- hives
- rash

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- in contact with meninges
- in the genital area

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Bactoshield® CHG 4%

NDC 11084-815-08

Surgical Scrub

Chlorhexidine Gluconate 4% Solution Antiseptic

Surgical Scrub

4% CHG

Antimicrobial

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

REORDER #1344-08

1344-06G(319)

51690

4BACT1GLBLB





Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)			CHLORHEXIDINE GLUCONATE	40 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
COCO DIETHANOLAMIDE (UNII: 92005F972D)				
GLUCONOLACTONE (UNII: WQ29KQ9POT)				
HYDROXYETHYL CELLULOSE (5000 MPAS AT 1%) (UNII: X70SE62ZAR)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
LAURAMINE OXIDE (UNII: 4F6FC4M8W)				
PEG-75 LANOLIN (UNII: 09179OX7TB)				
WATER (UNII: 059QF0KO0R)				
TRIDECYL ALCOHOL (UNII: 8I9428H868)				
Product Characteristics				
Color	yellow		Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-1344-08	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/1999	
2	NDC:0116-1344-24	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/1999	
3	NDC:0116-1344-34	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/1999	
4	NDC:0116-1344-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/1999	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA019125	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(0116-1344)