

BACTOSHIELD CHG- chlorhexidine gluconate solution
Xttrium Laboratories, Inc.

Bactoshield CHG[®] 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.

Bactoshield® CHG 4%

NDC 11084-815-03

Surgical Scrub

Chlorhexidine Cluconate 4% Solution Antiseptic

Non-sterile Solution

Surgical Scrub

4% CHG

Antimicrobial

For Single-Use

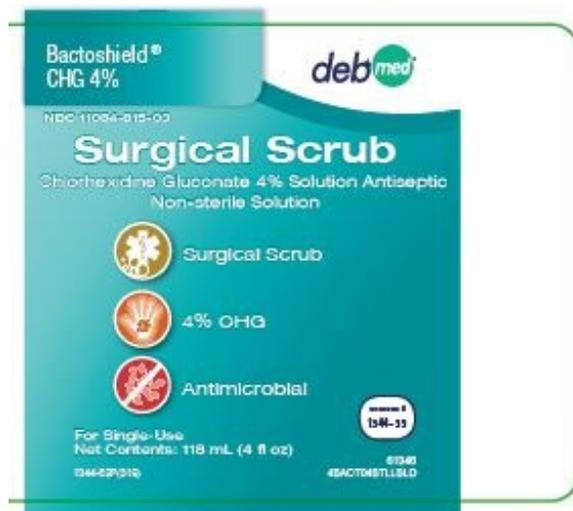
Net Contents: 118 mL (4 fl oz)

REORDER #1344-39

1344-52F(319)

61346

4BACT04BTLLBLD



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

Drug Facts

Active ingredient	Purposes
Chlorhexidine gluconate 4% solution	surgical hand scrub healthcare personnel handwash patient preoperative skin preparation skin wound and general skin cleansing

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 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



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.

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%

deb med

NDC 1084-815-34

Surgical Scrub

Chlorhexidine Gluconate 4% Solution Antiseptic



Surgical Scrub



4% CHG



Antimicrobial

NO. 1344-33

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



61340
1344-31H(319)
4BACT16BTL9LE

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)

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.

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

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

<p>Drug Facts (continued) 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 waterscrub for 3 minutes with about 5 mL of product and a wet brush, paying close attention to the nails, cuticles, and interdigital spacesa separate nail cleaner may be usedrinse thoroughlywash for an additional 3 minutes with 5 mL of product and rinse under running waterdry thoroughly <p>Healthcare personnel handwash:</p> <ul style="list-style-type: none">wet hands with waterdispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 secondsrinse 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 waterapply the minimum amount of product necessary to cover the skin or wound area and wash gentlyrinse again thoroughly <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 1-866-783-0422 Monday through Friday 8:00 AM to 4:30 PM EST</p> <p>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.</p> <p>Manufactured for: Deb USA Inc. Charlotte, NC 28217 1-866-783-0422 www.debmed.com Product Made in U.S.A.</p>	<p>Bactoshield® CHG 4%</p> <p>NDC 11084-815-24</p> <p>Surgical Scrub 4% Solution Antiseptic Chlorhexidine Gluconate</p> <p>Surgical Scrub</p> <p>4% CHG</p> <p>Antimicrobial</p> <p>Net Contents: 32 fl oz (946 mL)</p> <p>61341 1344-21H(319) 4BACT32BTLLBLB</p> <p>debm ed</p> <p>REORDER # 1344-24</p> 	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredient</th><th>Purposes</th></tr></thead><tbody><tr><td>Chlorhexidine gluconate 4% solution</td><td>surgical hand scrub healthcare personnel handwash skin wound and general skin cleansing</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 carehealthcare personnel handwash helps reduce bacteria that potentially can cause diseaseskin 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">whistling/difficulty breathingshockfacial swellinghivesrash <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 productin contact with meningitisin 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 waterwounds which involve more than the superficial layers of the skin should not be routinely treatedrepeated 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>	Active ingredient	Purposes	Chlorhexidine gluconate 4% solution	surgical hand scrub healthcare personnel handwash skin wound and general skin cleansing
Active ingredient	Purposes					
Chlorhexidine gluconate 4% solution	surgical hand scrub healthcare personnel handwash skin wound and general skin cleansing					

Bactoshield® CHG 4%

NDC 11084-815-08

Surgical Scrub

Chlorhexidine Gluconate 4% Solution Antiseptic

Surgical Scrub

4% CHG

Antimicrobial

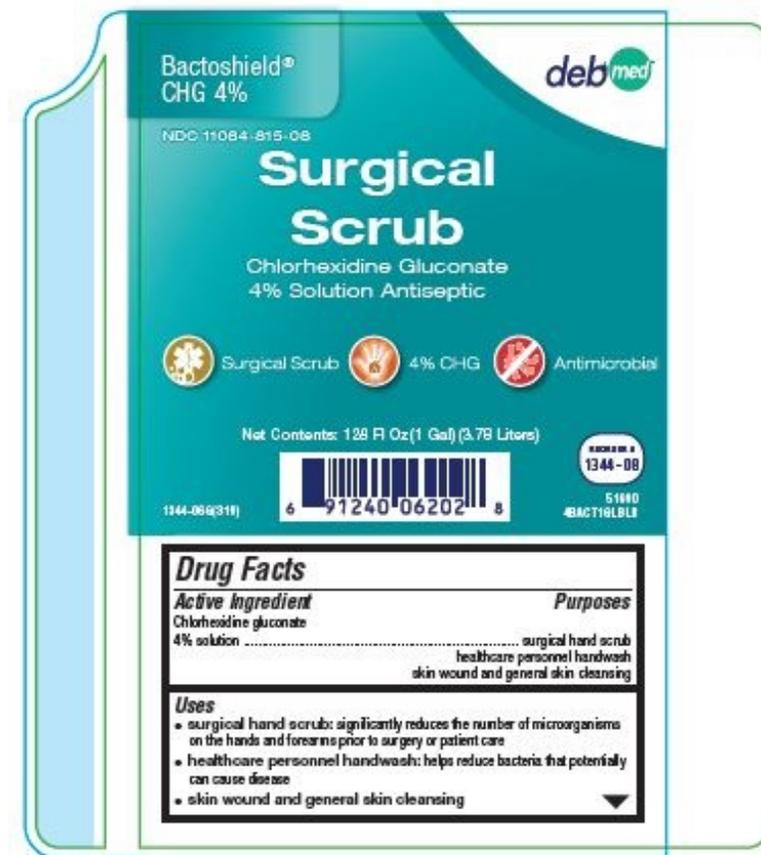
Net Contents: 128 fl oz (1 Gal) (3.78 Liters)

REORDER #1344-08

1344-06G(319)

51690

4BACT1GLBLB



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 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 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

Drug Facts (continued)**Healthcare personnel handwashes:**

- 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, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol.**Questions or comments?**

call 1-866-793-0422 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.

Manufactured for: Deb USA Inc.
Charlotte, NC 28217
1-866-793-0422
www.debmed.com

Product Made in U.S.A

BACTOSHIELD CHG

chlorhexidine gluconate solution

Product Information**Product Type**

HUMAN OTC DRUG

Item Code (Source)

NDC:0116-1344

Route of Administration

TOPICAL

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: 4F6FC4M18W)	
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)