

BETASEPT- antiseptic surgical scrub solution
Xttrium Laboratories, Inc.

BETASEPT Antiseptic Surgical Scrub

Chlorhexidine Gluconate 4%

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:** preparation of the patient's skin prior to surgery
- **skin wound and general skin cleansing**

Warnings

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, 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 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 and 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

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

Questions or comments?

call 1-888-827-0624 (8am-5pm, EST, Mon-Fri)

WARNING: Cancer - www.P65Warnings.ca.gov

NDC 67618-200-04

From the Makers of BETADINE® products

For External Use Only

Not for Retail Sale

For Professional and Hospital Use Only

Single Use

BETASEPT®

Antiseptic Non-Sterile Surgical Scrub

Chlorhexidine Gluconate 4%

Net Contents: 4 fl oz (118 mL)

Dist. by: Avrio Health L.P. Stamford, CT 06901-3431

4BET04BTLLBLG

4BET04BTLLBLG

Lift Here

Drug Facts	
Active ingredient Chlorhexidine gluconate 4% solution.....Antiseptic	Purpose Antiseptic

Uses
* surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care

WARNING: Cancer -
www.P65Warnings.ca.gov

NDC 67618-200-04
For External Use Only
Not for Retail Sale
For Professional and Hospital Use Only

BETASEPT®
Antiseptic Non-Sterile
Surgical Scrub

**Chlorhexidine 4%
Gluconate**

Net Contents:
4 fl oz (118 mL)

Dist. by: Avrio Health L.P.
Stamford, CT 06901-3431

Drug Facts (continued)

- 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 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
- 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 ▼

Drug Facts (continued)

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 ▼

Drug Facts (continued)
<ul style="list-style-type: none"> ■ repeat procedure for an additional 2 minutes and dry with a sterile towel
Skin wound and general skin cleansing
<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
Other information
<ul style="list-style-type: none"> ■ 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 1-888-827-0624 (9am-5pm, EST, Mon-Fri.)

304982-0A

NDC 67618-200-08

From the Makers of BETADINE® products

For External Use Only

Not for Retail Sale

For Professional and Hospital Use Only

BETASEPT®

Antiseptic Surgical Scrub

Chlorhexidine Gluconate 4%

Net Contents: 8 fl oz (237 mL)

Dist. by: Avrio Health L.P. Stamford, CT 06901-3431

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NDC 67618-200-08

For External Use Only
Not for Retail Sale
For Professional and Hospital Use Only

BETASEPT®
Antiseptic
Surgical Scrub

**Chlorhexidine
Gluconate 4%**

Net Contents:
8 fl oz (237 mL)

Dist. by: Avrio Health L.P.
Stamford, CT 06901-3431 304984-0A

From the
makers of
Betadine
products

Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate 4% 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
- 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. ▼



WARNING: Cancer - www.P65Warnings.ca.gov



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 ▼

Drug Facts (continued)
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 1-888-827-0624 (8am-5pm, EST, Mon-Fri.)

NDC 67618-200-16

From the Makers of BETADINE® products

For External Use Only

Not for Retail Sale

For Professional and Hospital Use Only

BETASEPT®

Antiseptic Surgical Scrub

Chlorhexidine Gluconate 4%

Net Contents: 16 fl oz (473 mL)

Dist. by: Avrio Health L.P. Stamford, CT 06901-3431

4BET16BTLLBLB

NDC 67618-200-16

For External Use Only

Not for Retail Sale

For Professional and Hospital Use Only

BETASEPT®

**Antiseptic
Surgical Scrub**

**Chlorhexidine
Gluconate 4%**

From the
makers of
Betadine®
products

Net Contents: 16 fl oz (473 mL)

Dist. by:

Avrio Health L.P.
Stamford, CT 06901-3431
304978-0A



Drug Facts

Active ingredient

Chlorhexidine gluconate

Purpose

4% solution Antiseptic

Uses

- surgical hand scrub: significantly reduce 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.

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



WARNING: Cancer - www.PoisonWarnings.ca.gov

Lift Here

Drug Facts (continued)

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°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 1-888-827-0624 (8am-5pm, EST, Mon-Fri.)

From the Makers of BETADINE® products

For External Use Only

Not for Retail Sale

For Professional and Hospital Use Only

BETASEPT®

Antiseptic Surgical Scrub

Chlorhexidine Gluconate 4%

Net Contents: 32 fl oz (946 mL)

Dist. by: Avrio Health L.P. Stamford, CT 06901-3431


4BET32BTLLBLB

NDC 67618-200-30

For External Use Only
Not for Retail Sale
For Professional and Hospital Use Only

BETASEPT®

Antiseptic Surgical Scrub



Chlorhexidine Gluconate **4%**

From the makers of Betadine® products

Net Contents:
32 fl oz (946 mL)

Dist. by:
Avrio Health L.P.
Stamford, CT 06901-3431 304978-0A

4BET32BTLLBLB

Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate 4% 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 handwashes: 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.
Do not use ■ if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
■ in contact with meringes ■ 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 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 ■ rinse again thoroughly
■ 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, triethyl alcohol.

Questions or comments? call 1-888-827-0624 (8am-5pm, EST, Mon-Fri)

WARNING: This product can expose you to chemicals including 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

NDC 67618-200-32

From the Makers of BETADINE® products

For External Use Only

Not for Retail Sale

For Professional and Hospital Use Only

BETASEPT®

Antiseptic Surgical Scrub

Chlorhexidine Gluconate 4%

Net Contents: 32 fl oz (946 mL)

Dist. by: Avrio Health L.P. Stamford, CT 06901-3431

4BET32PBTLBLB

NDC 67618-200-32

For External Use Only
Not for Retail Sale
For Professional and Hospital Use Only

BETASEPT®

Antiseptic Surgical Scrub
With Pump

3 67618-200-32 2

Chlorhexidine
Gluconate

4%

From the
makers of
Betadine®
products

Net Contents:
32 fl oz (946 mL)

Dist. by:
Avrio Health L.P.
Stamford, CT 06901-3431 304950-0A

4BET32PBTLLBLB

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
■ 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
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°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, triethyl alcohol.

Questions or comments? call 1-888-827-0624 (8am-5pm, EST, Mon-Fri.)

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WARNING: This product can expose you to chemicals including 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

BETASEPT

antiseptic surgical scrub solution

Product Information					
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)		NDC:0116-0200
Route of Administration		TOPICAL			
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Strength		Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)			CHLORHEXIDINE GLUCONATE		0.04 mg in 1 mL
Inactive Ingredients					
Ingredient Name				Strength	
COCO DIETHANOLAMIDE (UNII: 92005F972D)					
GLUCONOLACTONE (UNII: WQ29KQ9POT)					
ISOPROPYL ALCOHOL (UNII: ND2M416302)					
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)					
PEG-75 LANOLIN (UNII: 09179OX7TB)					
WATER (UNII: 059QF0KO0R)					
TRIDECYL ALCOHOL (UNII: 8I9428H868)					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0116-0200-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993		
2	NDC:0116-0200-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993		
3	NDC:0116-0200-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993		

4	NDC:0116-0200-30	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	
5	NDC:0116-0200-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	
6	NDC:0116-0200-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA019125	06/01/1993	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment			
Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0200)

Revised: 10/2020

Xttrium Laboratories, Inc.