

BETASEPT- antiseptic surgical scrub solution
Xttrium Laboratories, Inc.

XTT 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: Atlantis Consumer Healthcare Inc. Bridgewater, NJ 08807 USA

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4BET04BTLLBLH

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
Gluconate 4%**

Net Contents: 4 fl oz (118 mL)

Dist. by: Atlantis Consumer Healthcare Inc., Bridgewater, NJ 08807 USA
©2023 Atlantis Consumer Healthcare Inc.

Single Use

From the
makers of
BETADINE®
products

Drug Facts

Active ingredient **Purpose**

Chlorhexidine gluconate 4% Antiseptic

Uses

- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- patient preoperative skin preparation: for the preparation of the patient's skin prior to surgery
- 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 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.

Drug Facts (continued)

- 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

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)

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? 1-833-288-2684

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WARNING: Cancer - www.FdaWarnings.gov

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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:Atlantis Consumer Healthcare Inc. Bridgewater, NJ 08807 USA

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NDC 67618-200-08 For External Use Only Not for Retail Sale For Professional and Hospital Use Only		Drug Facts Active ingredient Purpose Chlorhexidine gluconate 4% solution Antiseptic		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.		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 Skin wound and general skin cleaning: ■ 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? 1-833-288-2684	
BETASEPT® Antiseptic Surgical Scrub Chlorhexidine Gluconate 4% <div>From the makers of Betadine® products</div>		Uses ■ 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	
Net Contents: 8 fl oz (237 mL) Dist. by: Atlantis Consumer Healthcare Inc. Bridgewater, NJ 08807 USA ©2023 Atlantis Consumer Healthcare Inc. 304984-0A		<div> <div> </div> <div> 4BET08BTLBLH 3 67618 20008 7 </div> </div>					

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: Atlantis Consumer Healthcare Inc. Bridgewater, NJ 08807 USA

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4BET16BTLLBLC

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%

Net Contents:
16 fl oz (473 mL)

Dist. by: Atlantis Consumer Healthcare Inc.
 Bridgewater, NJ 08807 USA
 ©2023 Atlantis Consumer Healthcare Inc.
 304976-0A

Drug Facts

Active ingredient Chlorhexidine gluconate
 4% solution Antiseptic

Purpose

Uses

- 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
- hives
- facial swelling
- rash

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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

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
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Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

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

Skin wound and general skin cleaning:

- 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? 1-833-288-2684

WARNING: Cancer - www.PoisonHelp.org

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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: Atlantis Consumer Healthcare Inc. Bridgewater, NJ 08807 USA

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4BET32PBTLBLC

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: Atlantis Consumer Healthcare Inc.
Bridgewater, NJ 08807 USA
©2023 Atlantis Consumer Healthcare Inc.

304978-0A
4BET3BTLLBL

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

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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?

1-833-288-2684



WARNING: Cancer - www.PoisonWarnings.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
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	

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	
	NDC:0116-0200-04	227 mL in 1 BOTTLE; Type 0: Not a Combination Product		

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)