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 seperate 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 priduct 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

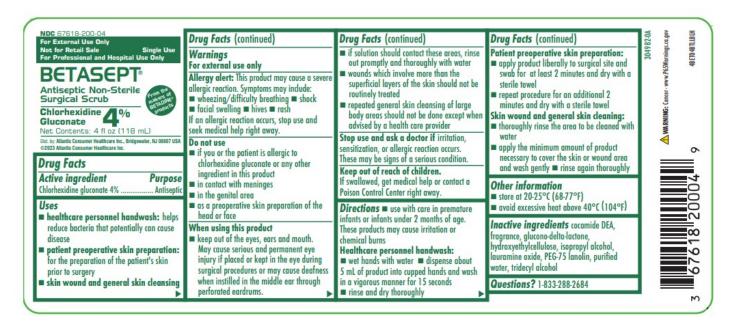
Chlorhexidine Gluconate 4%

Net Contents: 4 fl oz (118 mL)

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

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4BET04BTLLBLH



NDC 67618-200-08

From the Makers of BETADINE® products

For External Use Only

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For Professional and Hospital Use Only

BETASEPT®

Antiseptic Surgical Scrub

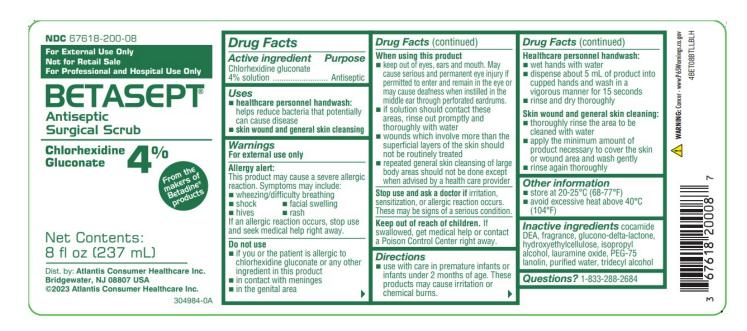
Chlorhexidine Gluconate 4%

Net Contents: 8 fl oz (237 mL)

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

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4BET08BTLLBLH



NDC 67618-200-16

From the Makers of BETADINE® products

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BETASEPT®

Antiseptic Surgical Scrub

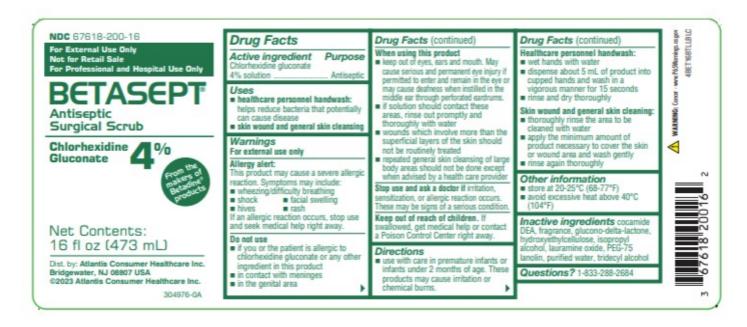
Chlorhexidine Gluconate 4%

Net Contents: 16 fl oz (473 mL)

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

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4BET16BTLLBLC



NDC 67618-200-32

From the Makers of BETADINE® products

For External Use Only

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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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4BET32PBTLLBLC





Chlorhexidine / 0/0 Gluconate





4BET32BTLLBLC

Drug Facts

septic

Purpose

For external use only

Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:

wheezing/difficulty breathing shock facial swelling shows reaction accure, stop use and seek medical help right away.

Do not use figure if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product

Directions were with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns Surgical hand scrub: when the data and forearms with water scrub for 3 minutes with about 5 mL. of product and a wet brush, paying close attention to the nails, outicles, and interdigital spaces as a separate nail cleaner may be used in the entire the product and a wet brush, paying close attention to the nails, outicles, and interdigital spaces as a separate nail cleaner may be used in the entire the product and a wet brush, paying close attention to the nails, outicles, and interdigital spaces as a separate nail cleaner may be used in the entire throughly healthcare personnel handwash: whether we had swith water displayed the product into cupped hands with water all dispense shout 5 mL of product into cupped hands and wash in a vigorous marrier for 15 seconds rinse end dry thoroughly Skin wound and general skin cleansing: thoroughly inse the area to be cleaned with water are product may be used. The product may be used to be cleaned with water are product may be used. The product may be used to be cleaned with water are product may be used.

Other information ■ store at 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F)

Inactive ingredients occamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulcee, isopropyl alcohol, lauraminoxide, PEG-75 lanolin, purified water, tridecyl alcohol.

Questions? 1-833-288-2684



WARNING: Cancer - www.P65Warninga.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

COCO DIETHANOLAMIDE (UNII: 92005F972D)

Ingredient Name Basis of Strength Strength

CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE -CHI ORHEXIDINE 0.04 ma UNII:R4KO0DY52L) **GLUCONATE** in 1 mL

Inactive Ingredients

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Strength		

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	227 ml in 1 DOTTLE. Tyma O. Nat a Cambination		

2	0200-08	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 I	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)

Revised: 4/2025 Xttrium Laboratories, Inc.