

**BACTOSHIELD CHG- chlorhexidine gluconate 2% solution**  
Xttrium Laboratories, Inc.

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**SCJ 4 oz 2% CHG Bactoshield**

***Drug Facts***

***Active ingredient***

Chlorhexidine gluconate 2% 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***

**For external Use Only**

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 under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- 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 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**

citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

**Questions or comments?**

call 1-800-587-3721

Monday through Friday 8:00 AM to 4:30 PM CST

**Laundering/Cleaning Instructions:**

Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

**Packaging****SCJ Professional**

Healthcare

**Bactoshield****CHG 2%**

NDC 11084-038-03

**Surgical Scrub****Chlorhexidine Gluconate 2% Solution Antiseptic****Non-Sterile Solution****Surgical Scrub****2% CHG****Antimicrobial**

REORDER#

1322-39

SAP # 4000011062

1322-52K(123)

2SCJ04BTLLBLA

**deb**

# SKIN CARE

## For Single Use

### Net Contents:

4 fl oz (118 mL)



Lift Here

Drug Facts	Purpose
<b>Active ingredient</b> Chlorhexidine gluconate 2% solution	Antiseptic
<b>Uses</b>	
■ 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	

### Drug Facts (continued)

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

### Warnings

For external use only

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- wheezing/difficult breathing
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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.

#### Surgical hand scrub:

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Manufactured for: SCJ Professional USA, Inc.  
Charlotte, NC 28217  
1-866-783-0422 [www.scjp.com](http://www.scjp.com)

 **WARNING:** Cancer – [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).  
Keep from freezing.

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**BACTOSHIELD CHG**

chlorhexidine gluconate 2% solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0116-0038
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	2 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>COCO DIETHANOLAMIDE</b> (UNII: 92005F972D)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0038-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019422	11/16/2022	

**Labeler** - Xttrium Laboratories, Inc. (007470579)

**Registrant** - Xttrium Laboratories, Inc. (007470579)

## Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0038)

Revised: 3/2023

Xttrium Laboratories, Inc.