

**BACTOSHIELD CHG- chlorhexidine gluconate 4% solution**  
**Xttrium Laboratories, Inc.**

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**SCJ 4oz 4% CHG Bactoshield**

***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
- **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 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**

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

**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 4%**

NDC 11084-039-03

**Surgical Scrub****Chlorhexidine Gluconate 4% Solution Antiseptic****Non-Sterile Solution****Surgical Scrub****4% CHG****Antimicrobial**

REORDER#

1344-39

**SAP # 4000011061**

**1344-52J(123)**

**4SCJ04BTLLBLA**

**deb**

## SKIN CARE

For Single Use

Net Contents:

4 fl oz (118 mL)

Lift Here

<b>Drug Facts</b>	
<b>Active ingredient</b> Chlorhexidine gluconate 4% solution	<b>Purpose</b> Antiseptic
<b>Uses</b>	
■ surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care	
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**Bactoshield®**  
**CHG 4%**

**Surgical Scrub**  
Chlorhexidine Gluconate 4% Solution Antiseptic  
Non-Sterile Solution

**Surgical Scrub**

**4% CHG**

**Antimicrobial**

REORDER #  
**1344-39**

SAP # 4000011061  
1344-623(123)  
4SCJ04BTLBLA

**Net Contents:**  
**4 fl oz (118 mL)**

**deb**  
single use

For Single Use

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## **Drug Facts** (continued)

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- skin wound and general skin cleansing

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Manufactured for: SCJ Professional USA, Inc.  
Charlotte, NC 28217  
1-888-783-0422 [www.scjp.com](http://www.scjp.com)

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

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.

**BACTOSHIELD CHG**

chlorhexidine gluconate 4% solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0116-0039
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

## Inactive Ingredients

Ingredient Name	Strength
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>COCO DIETHANOLAMIDE</b> (UNII: 92005F972D)	
<b>PEG-75 LANOLIN</b> (UNII: 09179OX7TB)	
<b>TRIDECYL ALCOHOL</b> (UNII: 8I9428H868)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-0039-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	11/21/2022	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-0039)

Revised: 3/2023

Xttrium Laboratories, Inc.