

**ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid**  
**Kinray Inc.**

-----

**Drug Facts**

**Active Ingredients**

Chlorhexidine Gluconate 4% Solution

**Purpose**

Antiseptic

**Uses**

**Healthcare Professional 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 genral skin cleaning**

**Warnings**

for external use only

**Do not use**

- if you are allerlic to chlorhexidine gluconate or any ohter ingredient
- in contact with meninges
- in genital area
- as a preoperative skin preparation of the head or face

**When using this product**

- keep out of eyes, ears, an mouth. Maycause seriously and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when installed in the middle ear thru perforated eardurms.
- 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 the underlying condition makes it necessary to reduce the bacterial population of skin

*Stop use and ask 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

**Warning**

This product contains a chemical known to the State of California to cause Cancer.

## **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 5ml of product into cupped hands and wash in vigorous manner for about 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 normal 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, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

### **Questions of comments?**

call 1-800-587-3721 Monday through Friday 8 AM to 4:30 PM CST

### **Package label and principal display panel**

Preferred Plus Pharmacy

NDC 61715-072-08

Antiseptic Skin Cleanser

(Chlorhexidine Gluconate 4% solution)

Antiseptic/Antimicrobial Skin Cleanser

for external use only

8FL OZ. (237 mL)

Do not use if seal is broken or missing



NDC 61715-072-08

# ANTISEPTIC SKIN CLEANSER

(CHLORHEXIDINE GLUCONATE 4% SOLUTION)

ANTISEPTIC / ANTIMICROBIAL SKIN CLEANSER

**FOR EXTERNAL USE ONLY**

KIN 929-216



8 FL. OZ. (237mL)

**DO NOT USE IF SEAL IS  
BROKEN OR MISSING**

Lift Here

## Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate 4% solution	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

### Warnings

For external use only

#### Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients
- 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.

### 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 the underlying condition makes it necessary to reduce the bacterial population of the skin

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.

Warning: This product contains a chemical known to the State of California to cause cancer.

### 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 about 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, tridacyl alcohol.

**Questions or comments?** call 1-800-587-3721, Monday through Friday, 8:00 AM to 4:30 PM CST.

4KPP08BTLBL

Distributed By: Kinray Inc.  
152-35 10th Avenue, Whitestone, NY 11357

All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

(c) 2013 Kinray Inc., All Rights Reserved, PREFERRED PLUS, PREFERRED PLUS ++++ and the PREFERRED PLUS logo are trademarks and/or registered trademarks of Kinray Inc. All other marks are property of their respective owners.



# ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61715-072
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0K00R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-072-08	237 mL in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	08/03/2013	

**Labeler** - Kinray Inc. (012574513)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(61715-072)