

ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid
Chain Drug Marketing Association Inc.

COMP Quality Choice 4% 8oz

Active Ingredients

Chlorhexidine gluconate 4% solution

Purpose

Antiseptic

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control center right away

Stop use and ask doctor if

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

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 a vigorous manner for about 15 seconds
- rinse and dry thoroughly

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, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol.

Questions or comments?

1-800-587-3721

Other Information

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING

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

Laundering/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products. Rinse completely and use only non-

chlorine detergents.

*This product is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiclens®.

Warning: Cancer - www.P65Warnings.gov

Laundering/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach.

*This product is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiclens®.

Package label and principal display panel

Quality Choice

NDC 63868-940-08

Compare to the active ingredient in HIBICLENS®*

Antiseptic Skin Cleanser

Antiseptic/Antimicrobial Skin Cleanser

Chlorhexidine Gluconate 4% Solution

Reduces Bacteria on the Skin

Net Contents: 8FL OZ (237 mL) BOTTLE

FOR EXTERNAL USE ONLY

DYE FREE

1061QC08LBLG

The image shows a detailed view of the product label for Antiseptic Skin Cleanser. The label is primarily green and white. At the top left is the 'QC QUALITY CHOICE' logo. To its right, it says 'NDC 63868-940-08' and 'Compare to the active ingredient in HIBICLENS®*'. The main title is 'Antiseptic Skin Cleanser' in large blue letters, with 'Antiseptic/Antimicrobial Skin Cleanser' below it. The active ingredient is 'Chlorhexidine Gluconate 4% Solution'. It claims to 'Reduce Bacteria on the Skin' and is 'FOR EXTERNAL USE ONLY' and 'DYE FREE'. A barcode is present with the number '6 35515 96757 1'. Below the barcode, it says 'DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING' and '8 fl oz (237 mL) BOTTLE'. The right side of the label contains a 'Drug Facts' panel with sections for 'Active ingredient Purpose', 'Uses', 'Warnings', 'Allergy alert', 'Do not use', 'Directions', 'When using this product', 'Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs.', 'Keep out of reach of children.', 'Other information', 'Inactive ingredients', and 'Questions?'. The 'Inactive ingredients' list includes cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, and tridecyl alcohol. At the bottom right, there is a 'WARNING: Cancer' symbol and text, and a 'SAFETY' symbol with 'CAUTION' and 'AVOID CONTACT WITH EYES, EARS AND MOUTH'.

Drug Facts	
Active ingredient Chlorhexidine gluconate 4% solution	Purpose Antiseptic
Uses <ul style="list-style-type: none">healthcare personnel handwash: helps reduce bacteria that potentially can cause diseaseskin wound and general skin cleansing	
Warnings For external use only	
Allergy alert: This product may cause a severe allergic reaction. Symptoms may include: <ul style="list-style-type: none">wheezing/difficulty breathingshockhivesfacial swellingrash If an allergic reaction occurs, stop use and seek medical help right away.	
Do not use <ul style="list-style-type: none">if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this productin contact with meningitisin the genital area	

Drug Facts (continued)	
When using this product <ul style="list-style-type: none">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 waterwounds which involve more than the superficial layers of the skin should not be routinely treatedrepeated 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 <ul style="list-style-type: none">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: <ul style="list-style-type: none">wet hands with waterdispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 secondsrinse and dry thoroughly	
Skin wound and general skin cleaning: <ul style="list-style-type: none">thoroughly rinse the area to be cleaned with waterapply the minimum amount of product necessary to cover the skin or wound area and wash gentlyrinse again thoroughly	
Other information <ul style="list-style-type: none">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? 1-800-587-3721	

WARNING: Cancer - www.P65Warnings.gov

SAFETY - AVOID CONTACT WITH EYES, EARS AND MOUTH

Distributed by: CDMA, Inc.
Novi, MI 48075
www.qualitychoice.com
Questions: 600-935-2362

1061QC08LBLG

ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-940
Route of Administration	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
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-940-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2014	02/28/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	05/01/2014	02/28/2027

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(63868-940)