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

Quality Choice Drug Facts

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 procider

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 of 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

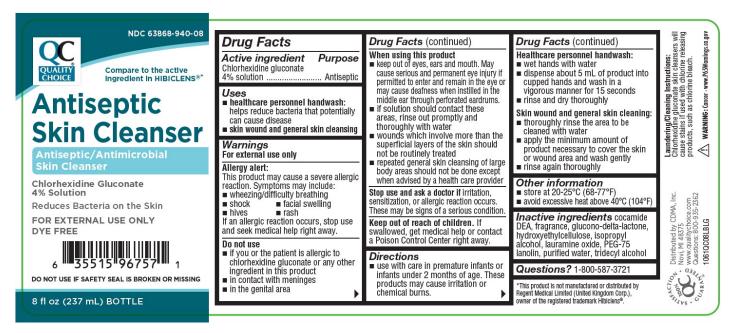
Reduces Bacteria on the Skin

Net Contents: 8FL OZ (237 mL) BOTTLE

FOR EXTERNAL USE ONLY

DYE FREE

1061QC08LBLG



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 - CHLORHEXIDINE - GLUCONATE in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)		
COCO DIETHANOLAMIDE (UNII: 92005F972D)		
PEG-75 LANOLIN (UNII: 091790X7TB)		
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
WATER (UNII: 059QF0KO0R)		

TRIDECYL ALCOHOL (UNII: 819428H868)
GLUCONOLACTONE (UNII: WQ29KQ9POT)

Packaging

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	#	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	

Marketing Information

Flanketing information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA019125	05/01/2014		

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)			

Revised: 11/2023 Chain Drug Marketing Association Inc.