ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid AmerisourceBergen Drug Corporation

Good Neighbor Pharmacy

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 cuase 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 cuase 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 healthcare 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 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?

call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

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.

*Good Neighbor Pharmacy® Antiseptic Skin Cleanser is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiclens®.

Package label and principal display panel

Good Neighbor Pharmacy

NDC 46122-137-34

Antiseptic Skin Cleanser

(Chlorhexidine Gluconate 4% solution)

Antiseptic/Antimicrobial Skin Cleanser

8 FL OZ. (237 mL)

ABC# 10103514

FOR EXTERNAL USE ONLY

DYE FREE

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING



Compare to the active ingredient in Hibiciens**

NDC 46122-137-34

Antiseptic

ANTISEPTIC/ ANTIMICROBIAL SKIN CLEANSER

8 fl oz (237 mL)

ABC# 10103514



FOR EXTERNAL USE ONLY DYE FREE

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING



4GNP08BTLLBLF



WARNING: This product can expose you to coconut oil disthanolamine condensate (cocamide disthanolamine), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Drug Facts

Active ingredient Chlorheddine gluconate 4% solution .

Purpose

Antiseptic

- 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

Drug Facts (continued)

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- If you or the patient is allergic to chlorheddine gluconate or any other ingredient in this product
- In contact with meninges
- In the genital area.

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 déafnéss 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 confact a Polson 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.

Drug Facts (continued)

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

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-detta-lactone trydroxyethylcellulose, 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.

*Good Neighbor Pharmacy® Antiseptic Skin Cleanser is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiciens®.



Distributed by: AmerisourceBergen 1300 Morris Drive, Chesterbrook, PA 19087 Questions or Concerns? www.mygnp.com

Good Neighbor Pharmacy

Compare to the active ingredient in Hiniclens®*

NDC 46122-137-43

Antiseptic Skin Cleanser

(CHLORHEXIDINE GLUCONATE 4% SOLUTION)

ANTISEPTIC/ANTIMICROBIAL SKIN CLEANSER

16 fl oz (473 mL)

ABC# 815811

FOR EXTERNAL USE ONLY

DYE FREE

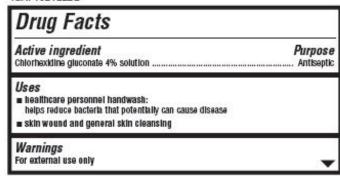
TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING





WARNING: This product can expose you to occount oil diethanolamine condensate (cocamide diethanolamine), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

4GNP16BTLLBL



Lift Here

Drug Facts (continued)

Allergy alert: This product may cause a severe allergic reaction.

Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hilves
- 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 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

Step 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.

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

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)

Drug Facts (continued)

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

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

Laundering/Cleaning instructions:

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ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-137
Route of Administration	TOPICAL		

l	Active Ingredient/Active Moiety			
l	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: 09179 O X7TB)			
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
WATER (UNII: 059QF0KO0R)			
TRIDECYL ALCOHOL (UNII: 819428H868)			
GLUCONOLACTONE (UNII: WQ29KQ9POT)			
LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:46122-137- 34	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 4/0 1/20 13		
2	NDC:46122-137- 43	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 19		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA0 19 125	0 4/0 1/20 13	

Labeler - AmerisourceBergen Drug Corporation (007914906)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment				
Name	Address	ID/FEI	Business Operations	
Xttrium Laboratories, Inc.		007470579	manufacture(46122-137)	