

ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate liquid

Cardinal Health

Leader 4% CHG 8oz

Drug Facts

Active ingredient

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

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 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 of 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 about 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

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 Regent Medical Limited (United Kingdom Corp.), owner of the registered trademark Hibiclens®.

WARNING: Cancer - www.P65Warnings.ca.gov

PDP

NDC 70000-0407-1

Leader

Antiseptic Skin Cleanser

Chlorhexidine Gluconate 4% Solution

Antiseptic/Antimicrobial Skin Cleanser

Great For Hand Hygiene

For Skin Wound and General Skin Cleansing

Compare To Hibiclens® active ingredients*

For External Use Only

8 fl (237 mL)

Tampering evident:

Do not use if shrink seal neckband is broken or missing

CIN 5454889 REV. 8/23

LEADER[®]

NDC 70000-0407-1

Antiseptic Skin Cleanser

Chlorhexidine Gluconate 4% Solution
Antiseptic / Antimicrobial Skin Cleanser


Great For Hand Hygiene
For Skin Wound and General Skin Cleansing

COMPARE TO HIBICLENS[®] active ingredient*

8 FL OZ (237 mL)

FOR EXTERNAL USE ONLY

TAMPERING EVIDENT:
DO NOT USE IF shrink seal neckband is broken or missing
CIN 5454889 REV. 8/23



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Drug Facts	Drug Facts (continued)	Drug Facts (continued)
<p>Active ingredient Purpose Chlorhexidine gluconate 4% solution Antiseptic</p> <p>Uses ■ healthcare personnel handwash: helps reduce bacteria that potentially can cause disease ■ skin wound and general skin cleansing</p> <p>Warnings For external use only</p> <p>Allergy alert: This product may cause a severe allergic reaction. Symptoms may include: ■ wheezing/difficulty breathing ■ shock ■ facial swelling ■ hives ■ rash</p> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>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</p>	<p>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</p> <p>Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions ■ use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</p>	<p>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</p> <p>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</p> <p>Other information ■ store at 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F)</p> <p>Inactive ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol</p> <p>Questions? 1-800-587-3721</p> <p>DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43077 www.myleader.com 1-800-200-6313</p>

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WARNING: Cancer - www.P65Warnings.ca.gov

ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0407
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0407-1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	01/01/2012	

Labeler - Cardinal Health (063997360)**Registrant** - Xttrium Laboratories, Inc (007470579)**Establishment**

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc		007470579	manufacture(70000-0407)