

ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid
Rite Aid Corporation

4% Rite Aid 8/16oz

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 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 a 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 5 mL of product into cupped hands and wash in a vigorous manner for about 15 seconds
- rinse and dry thoroughly
- 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, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol.

Questions or comments?

1-800-587-3721

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

WARNING: Cancer - www.P65Warnings.ca.gov

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

TAMPER-EVIDENT: Don't use if shrink seal neckband is broken or missing.

DISTRIBUTED BY: RITE AID,

200 Newberry Commons, Etter, PA 17319

www.riteaid.com

IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.

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Active ingredient

Chlorhexidine gluconate 4% solution

Purpose

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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 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 rinses 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)

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4RA16BTLLBLC

Package label and principal display panel

Compare to the active ingredient in Hibiclens®*

NDC 11822-3678-8

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE

4% SOLUTION

dye free

for external use only

TAMPER-EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

8 FL OZ (237mL)

Compare to the active ingredient in Hibiclens®*

NDC 11822-3678-8

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE 4% SOLUTION

dye free
for external use only

8 FL. OZ. (237 mL)

*THIS PRODUCT IS NOT MANUFACTURED OR DISTRIBUTED BY MÖLNLYCKE HEALTHCARE, OWNER OF THE REGISTERED TRADEMARK HIBICLENS®. TAMPER-EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
Active ingredient Purpose Chlorhexidine gluconate 4% solution Antiseptic	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	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
Uses <ul style="list-style-type: none">healthcare personnel handwash: helps reduce bacteria that potentially can cause diseaseskin wound and general skin cleansing	Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.	Other information <ul style="list-style-type: none">store at 20-25°C (68-77°F)avoid excessive heat above 40°C (104°F)
Warnings For external use only	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	Inactive ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol
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.	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.	Questions? 1-800-587-3721
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		

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

WARNING: CANCER - WWW.P65WARNINGS.CA.GOV

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DISTRIBUTED BY: RITE AID, 200 NEWBERRY COMMONS, ETTER, PA 17319 www.riteaid.com

Principal display panel

Compare to the active ingredient in Hibiclens®*

NDC 11822-3678-7

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE

4% SOLUTION

dye free

for external use only

TAMPER-EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

16 FL OZ (473 mL)

Compare to the active ingredient in Hibiclens®*

NDC 11822-3678-7

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE 4% SOLUTION

dye free
for external use only

16 FL. OZ. (473 mL)

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Drug Facts		Drug Facts (continued)		Drug Facts (continued)	
Active ingredient	Purpose	When using this product		Healthcare personnel handwash:	
Chlorhexidine gluconate 4% solution	Antiseptic	<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 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 		<ul style="list-style-type: none"> 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 	
Uses		Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.		Skin wound and general skin cleaning:	
<ul style="list-style-type: none"> healthcare personnel handwash: helps reduce bacteria that potentially can cause disease skin wound and general skin cleansing 		<ul style="list-style-type: none"> Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. 		<ul style="list-style-type: none"> 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 	
Warnings		Directions		Other information	
<p>For external use only</p> <p>Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> wheezing/difficulty breathing shock hives facial swelling rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> 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>use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</p>		<ul style="list-style-type: none"> store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F) 	
Inactive ingredients		Questions?		DISTRIBUTED BY:	
cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol		1-800-587-3721		RITE AID, 200 NEWBERRY COMMONS, ETTERS, PA 17319 www.riteaid.com	

Laundering/Cleaning Instructions: Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. **WARNING: CANCER - WWW.P65WAFRANKS.CA.GOV**

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ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-3678
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
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-3678-8	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2013	
2	NDC:11822-3678-7	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	01/01/2013	

Labeler - Rite Aid Corporation (014578892)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(11822-3678)

Revised: 11/2023

Rite Aid Corporation