

ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% solution
Rite Aid

4% Rite Aid 18oz FM

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 the 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 when advised by a healthcare 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 two months of age. These products may cause irritation or chemical burns.

Healthcare personnel handwash:

- wet hands with water
- dispense 4 full pumps (6 grams) of product into cupped hands and wash in a vigorous manner for 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-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 chlorine bleach.

WARNING: CANCER - WWW.P65WARNINGS.CA.GOV

Compare to the active ingredient in **Hibiclens®***

NDC 11822-0891-2

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

18 FL OZ (532 mL)

4RA18FM1061LBLB

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<p>Drug Facts</p> <p>Active ingredient Purpose Chlorhexidine gluconate 4% solution.....Antiseptic</p> <p>Uses <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> wheezing/difficulty breathing shock facial swelling hives rash If an allergic reaction occurs, stop use and seek medical help right away.</p>	<p>Drug Facts (continued)</p> <p>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 product in contact with the meninges in the genital area </p> <p>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 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 </p>	<p>Drug Facts (continued)</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 <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. Healthcare personnel handwash: <ul style="list-style-type: none"> wet hands with water dispense 4 full pumps (about 5 mL) of product into cupped hands and wash in a vigorous manner for 15 seconds rinse and dry thoroughly </p>	<p>Drug Facts (continued)</p> <p>Skin wound and general skin cleansing: <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 </p> <p>Other information <ul style="list-style-type: none"> 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, triethyl alcohol</p> <p>Questions? 1-800-587-3721</p>
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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

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

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

SATISFACTION GUARANTEE: If you're not satisfied, we'll happily refund your money.

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ANTISEPTIC SKIN CLEANSER			
chlorhexidine gluconate 4% solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0891
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
DIHYDROXYETHYL LAURAMINE OXIDE (UNII: JD265DM4U6)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0891-2	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	04/14/2021	

Labeler - Rite Aid (014578892)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc		007470579	api manufacture(11822-0891)

Revised: 11/2023

Rite Aid