ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid Walgreen Co.

Walgreens 1061

Active Ingredient

Chlorhexidine gluconate 4% Solution

Purpose

Antiseptic

Uses

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **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. Sypmtoms 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 of 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 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 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.

Surgical hand scrub:

- wet hands and forearms under running water
- scrub for 3 minutes with about 5 mL of product and a wet brush, paying close attention to the nails, cuticles, and interdigital spaces
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product and rinse under running water
- dry thoroughly

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 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?

call **1-800-925-4733**

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.

WARNING: This product contains a chemical (cocamide DEA) known to the State of California to cause cancer.

‡Walgreens Pharmacist Survey Study, November 2014

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

Distributed by: Walgreen Co.

200 Wilmot RD., Deerfield, IL 60015

100% Satisfaction Guaranteed

walgreens.com

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Package label and principal display panel

Well at Walgreens

NDC 0363-1061-08

Walgreens Pharmacist Recommended‡

Antiseptic Skin Cleanser

Chlorhexidine Gluconate 4% Solution/Antiseptic/Antimicrobial Skin Cleanser

Compare to the active ingredient in Hibiclens®‡‡

8 FL OZ. (237 mL)

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

4WA08BTLLBLF



Walgreens Pharmacist Recommended Walgreens Pharmacist Survey ^{‡†} This product is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiclens[®].

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Drug Facts

Active ingredient

Purpose

Chlorhexidine gluconate 4% solution Antiseptic

Uses

- surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or
- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- skin wound and general skin cleansing

Lift Here

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

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 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 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.

Surgical hand scrub:

- wet hands and forearms under running water
- scrub for 3 minutes with about 5 mL of product and a wet brush, paying close attention to the nails, cuticles, and interdigital spaces
- a separate nail cleaner may be used
- rinse thoroughly
 wash for an additional 3 minutes with 5 mL of product and rinse under running water
- dry thoroughly

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-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol.

Questions or comments? call 1-800-925-4733

W1061

ORG0918-F **REV-1018**

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.

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

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ITEM 454559 W10071-1018-F 11917^{||}12239[|] |||

Well at Walgreens

NDC 0363-1061-16

Walgreens Pharmacist Recommended‡

Antiseptic Skin Cleanser

Chlorhexidine Gluconate 4% Solution/Antiseptic/Antimicrobial Skin Cleanser

Compare to the active ingredient in Hibiclens®‡‡

16 FL OZ. (473 mL)

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

4WA16BTLLBLC



NDC 0363-1061-16

Walgreens

Compare to Hibiclens® active ingredient#

Dye-Free Antiseptic Skin Cleanser

CHLORHEXIDINE GLUCONATE 4%
SOLUTION / ANTISEPTIC / ANTIMICROBIAL SKIN CLEANSER

DYE FREE

Skin wound & general skin cleansing

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

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4WA16BTLLBLC

REV0718-RF

Drug Facts

Active ingredient

Purpose

Chlorhexidine gluconate 4% solution

.. Antiseptic

Hees

- surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- skin wound and general skin cleansing

Lift Here

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 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 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.

Surgical hand scrub:

- wet hands and forearms under running water
- scrub for 3 minutes with about 5 mL of product and a wet brush, paying close attention to the nails, cuticles, and interdigital spaces
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product and rinse under running water
- dry thoroughly

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-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol.

Questions or comments? call 1-800-925-4733

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.

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

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Walgreens

Dye-Free Antiseptic

Foaming Skin Cleanser

CHLORHEXIDINE GLUCONATE 4% SOLUTION /

ANTISEPTIC / ANTIMICROBIAL SKIN CLEANSER

Compare to Hibiclens® active ingredient

NDC 0363-1061-18

DYE FREE

Surgical hand scrub

Healthcare personnel handwash

Skin wound & general skin cleansing

18 FL OZ (532 mL)

4WA18FM1061LBL



Uses

- surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- skin wound and general skin cleansing

Wamings

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 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:

- wet hands and forearms with water
- scrub for 3 minutes with 4 full pumps (6 grams) of product and a wet brush paying close attention to the nails, cuticles, and interdigital spaces
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 4 full pumps (6 grams) of product and rinse under running water
- dry thoroughly

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?

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.

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey #This product is not manufactured or distributed by Regent Medical Limited Corporation, owner of the registered trademark Hibiclens®.

Carton

NDC 0363-1061-15

Walgreens, Co.

Chlorhexidine Gluconate 4% Solution

Antiseptic Skin Cleansing Kit

Distributed by:

Xttrium Laboratories, Inc.,

Mount Prospect, IL 60056

4WAL15INNERCTN

0.5 FL OZ (15 mL)





NET WT 0,17 lbs (79,62 g)

BEFORE WIRED THE PRODUCT CAREFULLY READ ALL WARRANGS AND POLICIN THE DIRECTORS IN THE DRUG ARCTS AND MICHAEL BREEF







Lidstock

NDC 0363-1061-15

Walgreens, Co.

Chlorhexidine Gluconate 4% Solution

Antiseptic Skin Cleansing Kit

Distributed by:

Xttrium Laboratories, Inc.,

Mount Prospect, IL 60056

4WAL15LIDSTOCK

0.5 FL OZ (15 mL)





Packet

NDC 0363-1061-15

Walgreens, Co.

Chlorhexidine Gluconate 4% Solution

Antiseptic Skin Cleansing Convenience Kit

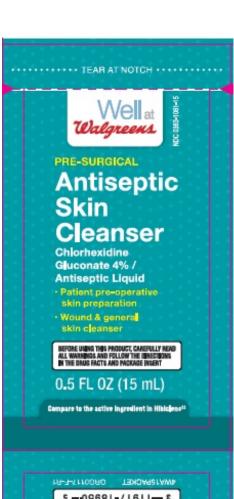
Distributed by:

Xttrium Laboratories, Inc.,

Mount Prospect, IL 60056

4WAL15PACKET

0.5 FL OZ (15 mL)







ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1061	
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
LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)	
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)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0363-1061- 08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2011		
2	NDC:0363-1061- 16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2011		
3	NDC:0363-1061- 15	15 mL in 1 KIT; Type 1: Convenience Kit of Co-Package	0 1/0 1/20 17		
4	NDC:0363-1061- 18	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/11/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA0 19 125	05/01/2011		

Labeler - Walgreen Co. (008965063)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment				
Name	Address	ID/FEI	Business Operations	
Xttrium Laboratories, Inc.		007470579	manufacture (0363-1061)	

Revised: 1/2021 Walgreen Co.