

ANTIMICROBIAL SKIN CLEANSER- chlorhexidine gluconate 2% solution liquid
Gojo Industries, Inc.

GOJO FMX-TFX-Provon

Drug Facts

Active ingredient

Chlorhexidine gluconate 2% solution

Purpose

Antiseptic

Uses

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

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 are allergic to chlorhexidine gluconate or any other ingredient in this product

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 through the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

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

Healthcare personnel handwash:

- wet hands with water
- dispense 5 mL of product (4 full strokes) into cupped hands and wash in a vigorous manner for 15 seconds
- dry thoroughly

Surgical hand scrub:

- wet hands and forearms with water
- scrub for 3 minutes with 5 mL of product (4 full strokes), with a wet brush, paying close attention to the nails, cuticles, and skin between the fingers
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product (4 full strokes) and rinse under running water and dry thoroughly

- store at 20-25°C (68-77°F)
- avoid excessive heat about 40°C (104°F)

Inactive ingredients

citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?

call 1-800-321-9647 Monday through Friday 8:30 AM to 5:00 PM

NDC 21749-106-89

Chlorhexidine Gluconate 2% Solution

Antimicrobial SKin Cleanser

Distributed by:

Gojo Industries, Inc.

Akron, OH 44309

330-255-6000

www.gojo.com



5304

NDC 21749-106-89



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Akron, OH 44309
Questions?
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330-255-6000
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Made in U.S.A.

40.5 fl oz (1.2 L)



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Skin Cleanser**

**Chlorhexidine Gluconate
2% Solution
Antiseptic**



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5306

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**Antimicrobial
Skin Cleanser**

**Chlorhexidine Gluconate
2% Solution
Antiseptic**





Drug Facts


Active ingredient

Chlorhexidine gluconate 2% solution

Purpose

Antiseptic

Uses

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

5304-643-B
BACKGOJOLBLC

Drug Facts (continued)

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 are allergic to chlorhexidine gluconate or any other ingredient in this product

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
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

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.



Drug Facts (continued)

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 5 mL of product (4 full strokes) into cupped hands and wash in a vigorous manner for 15 seconds
- dry thoroughly

Surgical hand scrub:

- wet hands and forearms with water
- scrub for 3 minutes with 5 mL of product (4 full strokes), with a wet brush, paying close attention to the nails, cuticles, and skin between the fingers
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product (4 full strokes) and rinse under running water and dry thoroughly

Other information • store at 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F)

Inactive ingredients citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments? call 1-800-321-9647 Monday through Friday 8:30 AM to 5:00 PM

NDC 21749-106-32

PROVON BRAND

Antimicrobial Skin Cleanser

Chlorhexidine Gluconate

2% Solution

Antiseptic

Distributed by:

GOJO Industries, Inc.

Akron, OH 44309

Questions?

Tel. 800-321-9647

*330-255-6000

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2PROV32BTLLBL

4104-12

Net Contents: 32 fl oz (1qt) (946 mL)



NDC 21749-106-32



Antimicrobial Skin Cleanser
Chlorhexidine Gluconate
2% Solution
Antiseptic

Distributed by:
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Akron, OH 44309
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* 330-255-6000
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2PROV32BTLLBLA

4104-12

Net Contents: 32 fl oz (1 qt) (946 mL)

Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate 2% solution	Antiseptic

Drug Facts (continued)

- 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. 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 are 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.

Drug Facts (continued)**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 5 mL of product (2 full strokes), with a wet brush, paying close attention to the nails, cuticles, and skin between the fingers
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product (2 full strokes) and rinse under running water and dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense 5 mL of product (2 full strokes) 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 citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water.

Questions or comments?

call 1-800-321-9647 Monday through Friday 8:00 AM to 5:00 PM EST

Laundry/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.

ANTIMICROBIAL SKIN CLEANSER

chlorhexidine gluconate 2% solution liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21749-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
HYDROXYETHYL CELLULOSE (2000 MPAS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-106-89	1200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2008	

2 | NDC:21749-106-32 | 946 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/01/2008

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019422	03/01/2008	

Labeler - Gojo Industries, Inc. (004162038)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(21749-106)

Revised: 6/2019

Gojo Industries, Inc.