PROVON ANTIMICROBIAL FOAM HANDWASH- chlorhexidine gluconate 2% solution Xttrium Laboratories, Inc.

2% GOJO ADX/LTX

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 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.

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 (6 full strokes) into cupped hands and wash in a vigorous manner for 15 seconds and rinse under running water and dry thoroughly

Surgical hand scrub:

- wet hands and forearms with water
- scrub for 3 minutes with 5 mL of product (6 full stokes), with a wet brush, paying close attention to the nails, cuticles, and skin between the fingers
- a seperate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product (6 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 add. 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

PROVON® Antimicrobial Foam Handwash

Chlorhexidine Gluconate 2% Solution - Antiseptic

GOJOADXFLBLC

8842-643-F

PROVON® Antimicrobia Foam Handwash Chlorhexidine Gluconate 2% Solution - Antiseptic Drug Facts Active ingredient Purpose Chlorhexidine gluconate 2% solution 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 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. 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 (6 full strokes) into cupped hands and wash in a vigorous manner for 15 seconds rinse and dry thoroughly Surgical hand scrub: . wet hands and forearms with water . scrub for 3 minutes with 5 mL of product (6 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 (6 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)

8842

NDC 21749-850-90

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PROVON®

Antimicrobial Foam Handwash with 2% CHG

Inactive ingredients citric acid, cocamide DEA,

GOJOADXFLBLC 8842-643-F

hydroxyethylcellulose, isopropyl alcohol,

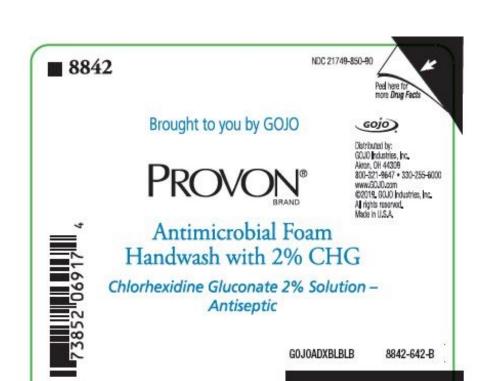
lauramine oxide, purified water

Chlorhexidine Gluconate 2% Solution - Antiseptic

42 fl oz (1250 mL)

GOJOADXBLBLB

8842-642-B



Drug Facts

Active ingredient

Purpose Antiseptic

Chlorhexidine gluconate 2% solution

 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

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.

42 fl oz (1250 mL)

· if you are allergic to chlorhexidine gluconate or any other ingredient in 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
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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.

Drug Facts (continued)

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.

Healthcare personnel handwash:

wet hands with water

dispense 5 mL of product (6 full strokes) into cupped hands and wash in a vigorous manner for 15 seconds and rinse under running water and dry thoroughly

Surgical hand scrub:

wet hands and forearms with water

 scrub for 3 minutes with 5 mL of product (6 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 (6 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 8:00 AM to 5:00 PM EST

PROVON ® Antimicrobial Foam Handwash Chlorhexidine Gluconate 2% Solution - Antiseptic GOJOLTXFLBLC 1922-643-F

PROVON® Antimicrobial Foam Handwash Chlorhexidine Gluconate 2% Solution - Antiseptic Drug Facts Purpose ... Antiseptic Active ingredient Chlorhacidine gluconate 2% solution 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 deathess when instilled in the middle earthrough 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 or infants under 2 months of age. These products may cause imitation or chemical burns. Healthcare personnel handwash: • wet hands with water • dispense 5 mL of product (6 full strokes) into cupped hands and wash in a vigorous manner for 15 seconds rinse and dry thoroughly Surgical hand scrub: • wet hands and forearms with water • scrub for 3 minutes with 5 mL of product (6 full strokes), with a wet brush, paying close attention to the nails, curicles, 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 (6 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, hydrocyethylcellulose, isopropyl alcohol, lauramine ocide, purified water GOJOCTXR.BLC| 1922-643-F

1922

NDC 21749-850-89

Brought to you by GOJO

PROVON®

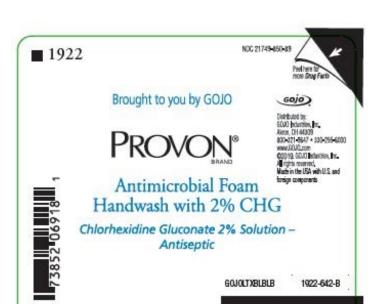
Antimicrobial Foam Handwash with 2% CHG

Chlorhexidine Gluconate 2% Solution - Antiseptic

40.5 fl oz (1200 mL)

GOJOLTXBLBLB

1922-642-B



40.5 fl oz (1200 mL)

Drug Facts

Active ingredient

Chlorhexidine gluconate 2% solution

Purpose . Antiseptic

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 surgical hand scrub: significantly reduces the number of microorganisms on the hands
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PROVON ANTIMICROBIAL FOAM HANDWASH

chlorhexidine gluconate 2% solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-8500	
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		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
COCO DIETHANOLAMIDE (UNII: 92005F972D)			
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)			
WATER (UNII: 059QF0KO0R)			

	Packaging			
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0116-8500- 89	1200 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/01/2016	
	NDC:0116-8500- 90	1250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/01/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA0 19 422	07/01/2016		

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment				
Name	Address	ID/FEI	Business Operations	
Xttrium Laboratories, Inc.		007470579	manufacture(0116-8500)	

Revised: 11/2019 Xttrium Laboratories, Inc.