PURELL ANTIMICROBIAL FOAM- chlorhexidine gluconate 2% solution liquid GOJO Industries, Inc.

Purell Foam Handwash

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 allergy reaction occurs, stop use and seek madical help right away.

Do not use

If you are allerigic 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 invlove more than the superficial layers of the skin

Stop use and ask doctor if

irritation, sensitization, or allerigic 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 cuase 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 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 acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

NDC 21749-225-53

Purell

FOAM HANDWASH

Chlorhexidine Gluconate 2% Solution - Antiseptic

Broad spectrum kill

Gentle on hands

2% CHG ANTIMICROBIAL FOAM

Distributed by:

GOJO Industries, Inc.

Akron, OH 44309

800-321-9647 • 330-255-6000

www.GOJO.com

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5742-643



Drug Facts

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Purpose Antisectic

Uses • healthcare personnel handwash:

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 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

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- 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.

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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
- andwash 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)

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

Fragrance-free

Dye-free

PURELL ANTIMICROBIAL FOAM

chlorhexidine gluconate 2% solution liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21749-225	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)			
WATER (UNII: 059QF0KO0R)			
LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)			
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)			
COCO DIETHANOLAMIDE (UNII: 92005F972D)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			

l	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 N	NDC:21749-225-53	535 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA0 19 422	0 2/0 1/20 18		

Labeler - GOJO Industries, Inc. (004162038)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment				
Name	Address	ID/FEI	Business Operations	
Xttrium Laboratories, Inc.		007470579	manufacture(21749-225)	

Revised: 6/2019 GOJO Industries, Inc.