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

Purell CS/ES System 2% CHG

Drug Facts

Active ingredient

chlorhexidine gluconate 2% solution

Purpose

Antiseptic

Uses

healthare personnel handwash: helps reduce bacteria that can potentially 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 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 permenant 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 5mL of product (6 full strokes) into cupped hands and wash in a vigorous manner for 15 seconds

rinse and dry throughly

Surgical hand scrub:

wet hands and forearms with water

scrub for 3 minutes with 5mL 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 5mL of product (6 full strokes) and rinse under running water and dry throughly

Other information

store at 20-25°C (68-77°F)

avoid excessive heat above 40°C (104°F)

Inactive ingredients

citric acid, comide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide. purified water

Purell

Healthcare

FOAM HANDWASH

2% CHG

Antimicrobial Foam

GOJOCSFLBLA

7887-641-F



NDC 21749-225-58

Purell

Healthcare FOAM HANDWASH 2% CHG

Antimicrobial Foam

Distributed by: GOJO Industries, Inc. Akron, OH 44309

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GOJOCS4BLBLA

5181-642-ES-B

42 fl oz (1250 mL)



NDC 21749-225-57

Purell

Healthcare FOAM HANDWASH 2% CHG

Antimicrobial Foam

Distributed by: GOJO Industries, Inc. Akron, OH 44309

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GOJOCS6BLBLA

6581-642-ES-B

40.5 FL OZ (1200 mL)



NDC 21749-225-56

Purell

Healthcare FOAM HANDWASH 2% CHG

Antimicrobial Foam

Distributed by: GOJO Industries, Inc. Akron, OH 44309

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GOJOCS8BLBLA

7881-641-ES-B

40.5 FL OZ (1200 mL)



HEALTHCARE

PURELL

FOAM

HANDWASH

CHLORHEXIDINE GLUCONATE

2% SOLUTION - ANTISEPTIC

40.5 fl oz (1200 mL)

GOJOESFLBL

7781-640-F



HEALTHCARE



FOAM **HANDWASH**

CHLORHEXIDINE GLUCONATE 2% SOLUTION - ANTISEPTIC

40.5 fl oz (1200 mL)

Drug Facts

Active ingredient Purpose Chlorhexidine gluconate 2% solution.... Antiseptic

Drug Facts (continued)

Uses . healthcare personnel handwash: helps reduce bacteria that potentially can cause disease surgical hand scrutc significantly reduces the number of microarcanisms on the hands and foreums prior to surgery or patient care

Warnings For external use only

Allergy alert: This product may cause a sewere allergic reaction. Symptoms may include:
• whearing/trifficulty-breathing • shock

 facial swelling • fives • rash
 if an allergic reaction occurs, stop use and seek medical help right away.

Do not use if you are all ergic to chlorhexidine gluconate or any other ingredient in this product

When using this product . leep 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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Drug Facts (continued)

Stop use and ask a dector if initiation, sensitization, or allergic reaction occurs. These may be signs of a serious

Keep out of reach of children. If small swed, 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
 sorub for 3 minutes with 5 mL of product [6 full strokes], with a wet brush, paying close attention to the nails, out cless and skin between the fingers
- a separate nail cleaner may be used in rinse thoroughly
 wash for an additional 3 minutes with 5 mL of product (6 full strokes) and rinse under running water and dry

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

Inactive ingredients citic acid, cosmide DEA, hydroyethyballulosa, isopropyl alcohol, lauramine oxida, purified water

GOJOESFLBL

7781-640-F

Purell

Healthcare

FOAM HANDWASH

2% CHG Antimicrobial Foam

40.5 fl oz (1200 mL)

GOJOES4BLBL

5081-640-B



NDC 21749-225-68

Purell

Healthcare

FOAM HANDWASH

2% CHG Antimicrobial Foam

40.5 fl oz (1200 mL)

GOJOES8BLBL

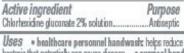
7781-640-B



Healthcare FOAM HANDWASH 2% CHG Antimicrobial Foam

NDC 21749-225-68

Okinbuksiloy: GOO habsinsa, Inc. Morn, CH 44.398 800-201-9647 + 330-255 - 600 news650 Ll.com — GCOTR, 60.00 Industries, Inc. Alrights seared, Madein the US Anith U.S. and Irosign companents.



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

Warnings For external use only

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Drug Facts (continued)

Stop use and ask a doctor if initation, 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 initiation or chemical burns.

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Inactive ingredients citic acid, cocarride DEA, hydroxyethylcelulose, isopropyl alcohol, lauramine oxide, purified water

GOJOESBBLBL

7781-640-B

ES8

40.5 fl oz (1200 mL)

Reorder No. 7781

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 (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
WATER (UNII: 059QF0KO0R)			
COCO DIETHANO LAMIDE (UNII: 92005F972D)			

HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)

LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-225- 58	1250 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 2/0 1/20 18	
2	NDC:21749-225- 57	1200 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 2/0 1/20 18	
3	NDC:21749-225- 56	1200 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 2/0 1/20 18	
4	NDC:21749-225- 64	1200 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2019	
5	NDC:21749-225-68	1200 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2019	

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)

$\pmb{Registrant - \text{Xttrium Laboratories, Inc. (007470579)}}$

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

Revised: 7/2019 GOJO Industries, Inc.