

PROVON FOAMING ANTIMICROBIAL HANDWASH WITH PCMX- chloroxylonol liquid
GOJO Industries, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

PROVON Foaming Antimicrobial Handwash with PCMX

Active ingredient

Chloroxylonol 0.5%

Purpose

Antimicrobial

Use

- Handwash to help decrease bacteria on the skin
- Recommended for repeated use

Warnings

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hands.
- Apply product and thoroughly cover hands with lather.
- Rinse well and dry hands completely.

Inactive ingredients

Water (Aqua), Alcohol, Lauric Acid, Ethanolamine, Dipropylene Glycol, Lactic Acid, Poloxamer 124, Isopropyl Alcohol, Sodium Metabisulfite, Sodium Sulfite, Tetrasodium EDTA, Sodium Sulfate, Fragrance (Parfum), Methylparaben, Propylparaben, Green 3 (CI 42053), Red 33 (CI 17200)

NDC 21749-541-97

Brought to you by GOJO
Llega a usted gracias a GOJO

PROVON®
BRAND

Foaming Antimicrobial
Handwash with PCMX
Jabón de manos antibacterial
en espuma con cloroxilenol

Distributed by, Distribuido por:
GOJO Industries, Inc., Akron, OH 44309
Tel: 800-321-8647
330-255-8000 www.GOJO.com
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Made in U.S.A., Hecho en los E.U.U.

1344

700 mL (23.6 US/ÉU FL OZ)

1344-640

Drug Facts

Active ingredient	Purpose
Chloroxilenol 0.5%	Antimicrobial

Uses • Handwash to help decrease bacteria on the skin • Recommended for repeated use

Warnings
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Stop use and ask a doctor if irritation or rash appears and lasts

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Drug Facts (continued)

Directions

- Wet hands
- Apply product and thoroughly cover hands with lather
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Inactive ingredients
Water (Aqua), Alcohol, Lauric Acid, Ethanolamine, Dipropylene Glycol, Lactic Acid, Poloxamer 124, Isopropyl Alcohol, Sodium Metabisulfite, Sodium Sulfite, Tetrasodium EDTA, Sodium Sulfate, Fragrance (Parfum), Methylparaben, Propylparaben, Green 3 (CI 42053), Red 33 (CI 17200)

PROVON FOAMING ANTIMICROBIAL HANDWASH WITH PCMX

chloroxilenol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21749-541
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.005 mg in 1 mL

Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)				
LAURIC ACID (UNII: 1160N9NU9U)				
MONOETHANOLAMINE (UNII: 5KV86114PT)				
DIPROPYLENE GLYCOL (UNII: E107L85C40)				
LACTIC ACID (UNII: 33X04XA5AT)				
POLOXAMER 124 (UNII: 1S66E28KXA)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
SODIUM METABISULFITE (UNII: 4VON5FNS3C)				
SODIUM SULFITE (UNII: VTK01UQK3G)				
EDETATE SODIUM (UNII: MP1J8420LU)				
SODIUM SULFATE (UNII: 0YPR65R21J)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-541-53	535 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2013	
2	NDC:21749-541-97	700 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2013	
3	NDC:21749-541-89	1200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2013	
4	NDC:21749-541-90	1250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2013	
5	NDC:21749-541-20	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2013	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333E	03/01/2013	

Labeler - GOJO Industries, Inc. (004162038)

Establishment			
Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		036424534	manufacture(21749-541)

Establishment			
Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		088312414	label(21749-541) , pack(21749-541)