

REGIMEN ANTIMICROBIAL- chloroxylenol soap

HealthLink

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.

Active ingredient

Chloroxylenol 0.5% w/w

Purpose

Antimicrobial

Keep out of reach of children

In case of accidental ingestion, seek medical attention or contact a poison control center immediately.

Uses

- specially formulated for the sensitive skin of today's healthcare professional
- protects hands from germs and bacteria
- antimicrobial hand cleaner
- for repeated washings on a daily basis

Warnings

For external use only

When using this product

- do not use in or near eyes

Directions

□ wet hands □ apply small amount □ wash hands vigorously □ rinse thoroughly.

Other information

□ store at room temperature

Inactive ingredients:

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Glycol Stearate, PEG 120 Methyl Glucose Dioleate, DMDM Hydantoin, Fragrance, Methyl Paraben, Propyl Paraben, Methylchloroisothiazolinone (and) Methylisothiazolinone, FD&C Blue #1.

PRINCIPAL DISPLAY PANEL - 3785 mL Bottle Label

REGIMEN

Antimicrobial Antiseptic Hand Wash

Contains 0.5% PCMX (Chloroxylenol), broad spectrum antimicrobial agent

Manufactured for PSS World Medical, Inc.
4345 Southpoint Blvd, Jacksonville, FL 32216

Net Contents 1 Gallon (3.78 L)



Antimicrobial Antiseptic Hand Wash

Contains 0.5% PCMX (Chloroxylenol), broad spectrum antimicrobial agent

Comments or Questions about Regimen Products? 800-777-4908
Manufactured for PSS World Medical, Inc.
4345 Southpoint Blvd., Jacksonville, FL 32216
Made in the USA • www.myselectionline.com

Drug Facts	
Active ingredient Chloroxylenol 0.5% w/w	Purpose Antimicrobial
Uses # specially formulated for the sensitive skin of today's healthcare professional # protects hands from germs and bacteria # antimicrobial hand cleaner # for repeated washings on a daily basis	
Warnings For external use only When using this product: # do not use in or near eyes Keep out of reach of children. In case of accidental ingestion, seek medical attention or contact a poison control center immediately.	

Drug Facts (Continued)	
Directions # wash hands thoroughly # use thoroughly	
Other information # store at room temperature	
Inactive ingredients: Water, Sodium Laureth Sulfate, Glycerol, Cocamidopropyl Betaine, Sodium Chloride, Glycol Stearate, PEG-120 Methyl Glucose Dioleate, DMDM Hydantoin, Methyl Paraben, Propyl Paraben, Fragrance, Methylchlorothiazolinone (and) Methylisothiazolinone, FD&C Blue #1.	

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GLR-01-0425-1

Net Contents 1 Gal (3.78 L)
Reorder # 198



REGIMEN ANTIMICROBIAL

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63843-547
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	5 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63843-547-25	532 mL in 1 BOTTLE, PLASTIC		
2	NDC:63843-547-28	3785 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/24/2013	

Labeler - HealthLink (807714126)

Revised: 9/2013

HealthLink