PANROSA ANTIBACTERIAL HAND ROSE- chloroxylenol gel
Panrosa Enterprises, 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.

Panrosa Antibacterial Hand Soap - Rose

Drug Facts

Active ingredient

Chloroxylenol 0.25%

Purpose

Antibacterial

Uses

- for hand washing to decrease bacteria on the skin

Warnings

For external use only.

When using this product

- avoid contact with eyes. In case of eye contact, flush with water.

Stop use and ask a doctor if

- irritation and redness develops.

If pregnant or breast-feeding,

ask a health professional before use

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- pump into hands, wet as needed
- lather vigorously for at least 15 seconds
- wash skin, rinse and dry thoroughly

Inactive ingredients

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Cocamide MEA, Glycerin, Glycol Stearate, Sodium Chloride, PEG-150 Distearate, Citric Acid, Fragrance, Methylisothiazolinone, Methylchloroisothiazolinone, Disodium EDTA, D&C Red NO. 33 FD&C Red No.4.

Package Labeling:

Transparent formulation

PANROSA ANTIBACTERIAL HAND ROSE

chloroxylenol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50302-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	2.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50302-016-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/01/2020	

Labeler - Panrosa Enterprises, Inc. (859957578)

Revised: 8/2020 Panrosa Enterprises, Inc.