

PANROSA ANTIBACTERIAL BAR- chloroxylenol soap

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 Bar Soap

Drug Facts

Active ingredient

Chloroxylenol 0.25%

Purpose

Antibacterial

Uses

- For 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.

Keep out of reach of children.

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

Directions

- wet bar with water
- lather vigorously and wash skin
- rinse and dry thoroughly

Inactive ingredients

SODIUM COCOATE, SODIUM PALMATE, WATER, GLYCERIN, SODIUM CHLORIDE, TITANIUM DIOXIDE, BHT, EDTA, FRAGRANCE, TRICLOCARBAN, RETINYL PALMITATE, TOCOPHERYL ACETATE, FD&C YELLOW NO. 5, FD&C RED NO. 4

Package Labeling:



PANROSA ANTIBACTERIAL BAR

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50302-014
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 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM COCOATE (UNII: R1TQH25F4I)	

SODIUM PALMATE (UNII: S0A6004K3Z)
WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
EDETIC ACID (UNII: 9G34HU7RV0)
TRICLOCARBAN (UNII: BGG1Y1ED0Y)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
FD&C RED NO. 4 (UNII: X3W0AM1JLX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50302-014-90	90 g in 1 BOX; Type 0: Not a Combination Product	06/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/15/2020	

Labeler - Panrosa Enterprises, Inc. (859957578)

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Panrosa Enterprises, Inc.