

ROYAL ANTIBACTERIAL (MANGO)- triclosan gel

Filo America

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

Triclosan 0.15%

Purpose

Antibacterial

Uses

for handwashing 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

- pump into hands
- lather vigorously for at least 15 seconds
- rinse and dry thoroughly.

Inactive Ingredients

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Lauryl Sulfate, Sodium Chloride, Fragrance, Citric Acid, Peg-150 Distearate, Tetrasodium Edta, FD&C Yellow No.5, FD&C Blue No.1



65x76mm

ROYAL ANTIBACTERIAL (MANGO)

triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50438-601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	1.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLCHLOROISOThIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOThIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50438-601-01	221 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/05/2015	

Labeler - Filo America (943873703)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Liyuan Daily Chemical Products Co., Ltd.		530766098	manufacture(50438-601)

Revised: 6/2015

Filo America