FASTRIN INFECTION CONTROL SKIN REPAIR- benzethonium chloride ointment Aidance Skincare & Topical Solutions, LLC

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.

Drug Facts

Active Ingredient

Benzethonium Chloride 0.2%

Purpose

Topical Antiseptic

Uses

Helps reduce the risk of skin infection.

Warnings

For external use only. When using this product do not get into eyes. **Stop use and ask a doctor if** condition worsens, symptoms last more than 7 days or clear up and occur again within a few days. **Do not use** on deep or puncture wounds, animal bites or serious burns.

Keep out of reach of children.

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

Directions

Clean and dry affected skin. For wound care, apply ointment liberally at least once daily, then cover with sterile bandaging. For barrier protection, massage into skin 2 to 4 times daily. Store at room temperature.

Inactive Ingredients

Beeswax, Cottonseed Oil, Jojoba Seed Oil, Magnesium Oxide, Manuka Honey, Silver Oxide, Zinc Oxide

PRINCIPAL DISPLAY PANEL - 50g Tube

Fastrin

Infection Control

Skin Repair Ointment

Net WT 50g (1.76 oz.)



FASTRIN INFECTION CONTROL SKIN REPAIR

benzethonium chloride ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-602
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHO NIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.2 g in 100 g		

Inactive Ingredients				
Ingredient Name	Strength			
COTTONSEED OIL (UNII: H3E878020N)				
HO NEY (UNII: Y9 H1 V 576 FH)				
JOJOBA OIL (UNII: 724GKU717M)				
MAGNESIUM O XIDE (UNII: 3A3U0 GI71G)				

SILVER OXIDE (UNII: 897WUN6G6T)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-602-10	10 g in 1 JAR; Type 0: Not a Combination Product	06/01/2017	
2	NDC:24909-602-50	50 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/01/2017		

Labeler - Aidance Skincare & Topical Solutions, LLC (018950611)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-602), label(24909-602)	

Revised: 6/2017 Aidance Skincare & Topical Solutions, LLC