

TEA TREE ANTISEPTIC - melaleuca alternifolia ointment
Integria Healthcare US Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Melaleuca Alternifolia (Tea Tree) Leaf Oil 5%

Antiseptic

protects cuts, abrasions, cracked dry skin, chapped lips and other minor wounds against infection

For external use only

In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.

Stop use and ask a doctor if redness, irritation or pain persists or increases, or if infection occurs.

Keep out of reach of children, if swallowed get medical help or contact a Poison Control Center right away.

- clean the affected area
- apply small amount two or three times a day
- may be covered with a sterile bandage

store below 86 degrees F

Beeswax, Canola Oil, Copernicia Cerifera (Carnauba) Wax, Macadamia Integrifolia Seed Oil, Tocopherol



TEA TREE ANTISEPTIC			
melaleuca alternifolia ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51257-644
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TEA TREE OIL (UNII: VIF565UC2G) (TEA TREE OIL - UNII:VIF565UC2G)		TEA TREE OIL	2.5 g in 50 g
Inactive Ingredients			
Ingredient Name		Strength	
YELLOW WAX (UNII: 2ZA36H0S2V)			

CANOLA OIL (UNII: 331KBJ17RK)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
MACADAMIA OIL (UNII: 515610SU8C)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51257-644-01	50 g in 1 JAR		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		02/01/2011		

Labeler - Integria Healthcare US Inc. (962379454)

Registrant - Integria Healthcare US Inc. (962379454)

Establishment			
Name	Address	ID/FEI	Business Operations
Integria Healthcare (Ballina)		750660367	manufacture

Revised: 3/2011

Integria Healthcare US Inc.