THURSDAY PLANTATION - tea tree antiseptic ointment Integria Healthcare Ballina

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

Uses: 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.

Antiseptic

Directions: 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.

Thursday Plantation

Australia's Original

Tea Tree Antiseptic

With Vitamin E

Distributed By: Integria Healthcare Australia Pty Ltd 8 Clunies Ross Court Eight Mile Plains, QLD 4113 Australia www.thursdayplantation.com USA Phone: 1-866-273-0377

Made in Australia



Inactive Ingredients: Cetearyl Alcohol, Mineral Oil, Paraffin, Sodium Lauryl Sulfate, Tocopheryl

THURSDAY PLANTATION

tea tree antiseptic ointment

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:66141-644

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	3 g in 50 g

Packaging

r ucing mg					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:66141-644-55	50 g in 1 JAR			

Marketing Information

Walketing information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		03/01/2010		

Labeler - Integria Healthcare Ballina (750660367)

Registrant - Integria Healthcare Australia (741396386)

Establishment

Littonishment					
Name	Address	ID/FEI	Business Operations		
Integria Healthcare Ballina		750660367	manufacture		

Establishment						
Name	Address	ID/FEI	Business Operations			
Integria Healthcare Australia		741396386	relabel			

Revised: 2/2010 Integria Healthcare Ballina