TEA TREE ANTISEPTIC - melaleuca alternifolia oil 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 100%

Antiseptic

treats minor cuts, minor burns, scrapes, abrasions, insect bites and stings.

For external use only

- avoid contact with eyes, mouth, ears and other sensitive areas of the body
- if contact occurs, rinse thoroughly with water

Stop use and ask a doctor if condition worsens or does not improve within 7 days.

Keep out of reach of children

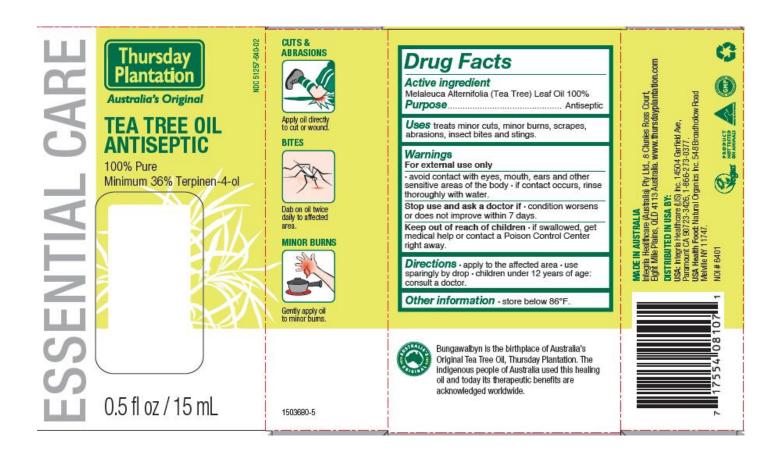
- if swallowed, get medical help or contact a Poison Control Center right away.
- apply to the affected area
- use sparingly by drop
- children under 12 years of age: consult a doctor

store below 86 degrees F

Tea Tree Oil Antiseptic

100% Pure

Minimum 36% Terpinen-4-ol





None.

TEA TREE ANTISEPTIC

melaleuca alternifolia oil

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51257-640
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	15 mL in 15 mL	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51257-640-01	10 mL in 1 BOTTLE		
2	NDC:51257-640-02	15 mL in 1 BOTTLE		
3	NDC:51257-640-03	25 mL in 1 BOTTLE		
4	NDC:51257-640-04	50 mL in 1 BOTTLE		

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.