TEA TREE ANTISEPTIC - tea tree oil 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.

Drug Facts

Active ingredient

Melaleuca Alternifolia (Tea Tree) Leaf Oil 5%

Purpose

First Aid Antiseptic

Uses

First aid to help protect against infection in minor cuts, scrapes and burns.

Warnings

For external use only

Do not Use

- in the eyes or apply over large areas of the body
- longer than 1 week unless directed by a doctor.

Ask a doctor before use if you have

deep or puncture wounds, animal bites, or serious burns.

Stop use and ask a doctor if

condition persists or worsens.

Keep out of reach of children.

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

Directions

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

Other information

• store below 86 F.

Inactive ingredients

Paraffin white soft, Mineral oil, Cetostearyl alcohol, dl-alpha tocopheryl acetate

DISTRIBUTED BY: Integria Healthcare (US) Inc., Paramount CA 90723-3426.

USA Health Food: Natural Organics Inc, 548 Broadhollow Road Melville NY 11747

MADE IN AUSTRALIA

Principal Display Panel

NDC 51257-642-02

Thurs day Plantation

Australia's Original

TEA TREE ANTISEPTIC OINTMENT

First aid to help protect against infection in minor cuts, scrapes and burns

Net Wt 1.76 oz (50 g)



TEA TREE ANTISEPTIC

tea tree oil ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51257-642
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	50 mg in 1 g

nactive Ingredients		
Ingredient Name	Strength	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
MINERAL OIL (UNII: T5L8T28FGP)		

PARAFFIN (UNII: 1900E3H2ZE)

.ALPHA.-TO CO PHERO L ACETATE, DL- (UNII: WR1WPI7EW8)

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51257-642-02	50 g in 1 JAR		

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		08/27/2013		

Labeler - Integria Healthcare (US) Inc (962379454)

Revised: 8/2013 Integria Healthcare (US) Inc