BIO BUTE - tea tree oil and eucalyptus oil oil Medivet Pty Ltd

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.

Active ingredient

Tea Tree Oil (Melaleuca Alternifolia) - 4.25% (42.5 mg/ml) Eucalyptus Oil (E. Polybractea) - 3.86% (38.6 mg/ml)

Uses

Massage Oil to assist with relief of joint and muscle pain

Warnings

For External and Animal Use Only

Keep Out of Reach of Children

Keep Out of Reach of Children. In case of accidental ingestion, get medical help or contact a Poisons Control Center right away

Inactive Ingredient Section

Olive Oil (INCI name: Olea Europaea (Olive) Oil)

Vanilla (INCI Name: Vanillin)

Package Label Principal Display Panel

For Animal Use Only

Store below 30 degrees C / 86 degrees F

Manufactured By Elmore Oil Company 1/70 Powells Av, VIC 3550 Australia. For Medivet Veterinary Supplies A4/101 Rookwood Road. Yagoan NSW 2199



BIO BUTE

tea tree oil and eucalyptus oil oil

Product Information

Product TypeOTC ANIMAL DRUGItem Code (Source)NDC:51083-100(NDC:43979-400)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength			
TEA TREE OIL (UNII: VIF565UC2G) (TEA TREE OIL - UNII:VIF565UC2G)	TEA TREE OIL	42.5 mg in 1 mL			
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	38.6 mg in 1 mL			

Inactive Ingredients

Ingredient Name Strength

Olive Oil (UNII: 6UYK2W1W1E)

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51083-100-00	125 mL in 1 BOTTLE, PLASTIC		
2 NDC:51083-100-01	500 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/15/2012	

Establishment				
Name	Address	ID/FEI	Business Operations	
Elmore Oil Company Pty Ltd		755881968	manufacture, analysis, api manufacture	

Revised: 9/2012 Medivet Pty Ltd