OUT BACK PAIN RELIEF - tea tree oil and eucalyptus oil oil Elmore Oil Company 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 Ingredients

Tea Tree Oil (Melaleuca Alternifolia) - 4.25% (42.5 mg/ml)

Eucalyptus Oil (E. Polybractea) - 3.86% (38.6 mg/ml)

Purpose

Massage Oil to assist with relief of joint and muscle pain

Indication and Usage

Temporary relief of joint and muscle pain, including lower back pain

Dosage and Administration

Apply a small amount of Out Back Pain Relief Oil to the pain affected area and gently massage in until fully absorbed. Use before and after activity for maximum relief.

Warnings

For external use only.

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

Inactive Ingredients

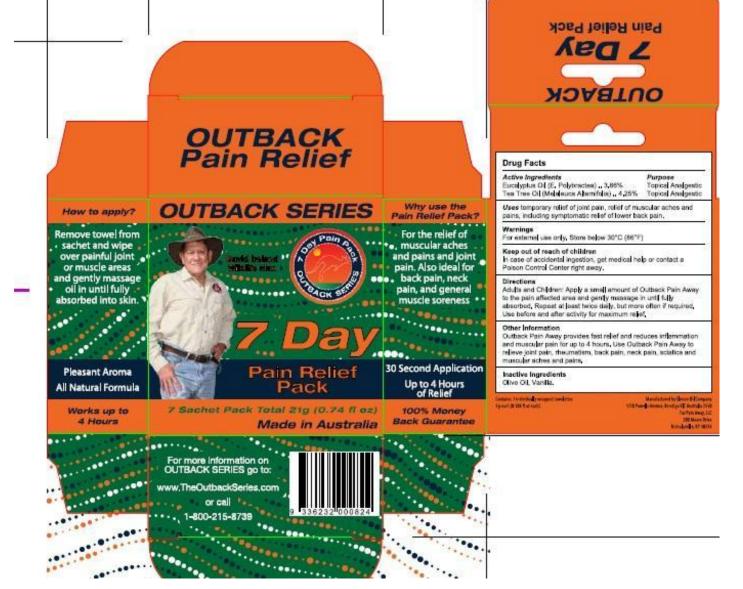
Olive Oil (INCI name: Olea Europaea (Olive)

Vanilla (INCI Name: Vanillin)

Keep out of Reach of Children

Keep Out of Reach of Children

Product Label





- Muscle Strain
- Back Pain



Manufactured by Elmore Oil Company 1/70 Powells Ave, Bendigo VIC Australia 3550 For Pain Away, ⊞€ 200 Moore Drive Nicholasville, KY 40356



OUT BACK PAIN RELIEF

tea tree oil and eucalyptus oil oil

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43979-550		
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	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)			

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:43979-550-01	3 mL in 1 POUCH				
2	NDC:43979-550-03	50 mL in 1 BOTTLE				

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10 / 0 1 / 20 12	

Labeler - Elmore Oil Company Pty Ltd (755881968)

Revised: 9/2012 Elmore Oil Company Pty Ltd