

OUT BACK PAIN RELIEF- eucalyptus oil and tea tree oil oil
Ultra Mix (Aust) 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](#).

Out Back Pain Relief

Actives

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

Eucalyptus Oil (Eucalyptus radiata) - 3.86% (38.6 mg/ml)

Inactives

Olive oil and Vanilin

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 Elmore 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.

If pregnant or breast feeding ask health care professional before use.

Keep out of reach from children.

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Product label

- Joint Pain
- Back Pain
- Muscular Pain



Pain Away, LLC
 200 Moore Drive
 Nicholasville, KY 40358
 Phone: 1-800-215-8739
 www.TheOutbackSeries.com

Drug Facts (continued)

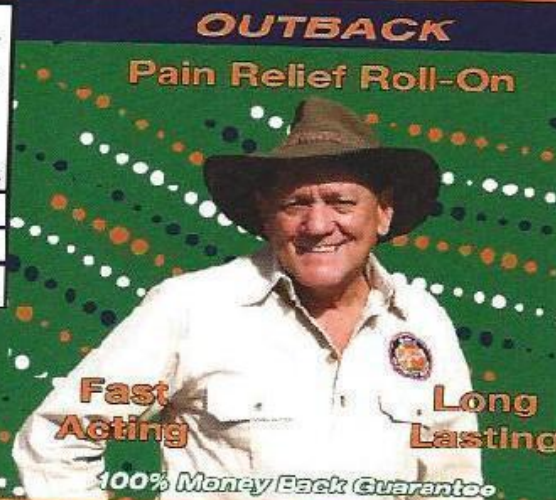
Directions

Adults and children 2 years of age or older: apply a small amount to the pain affected area and massage in until fully absorbed. ■ Repeat at least twice daily, and up to 4 times if required.
 ■ Children under 2 years of age consult a doctor.

Other Information ■ Store below 30 C (98 F)

Inactive Ingredients Olive Oil, Vanillin

Questions or comments 1-800-215-8739



Drug Facts

Active Ingredients	Purpose
Eucalyptus Oil 3.86%	External Analgesic
Tea Tree Oil 4.25%	External Analgesic

Uses Temporary relief of minor pain associated with ■ Joint Pain ■ Muscle Strain ■ Simple Back Ache

Warnings

■ For external use only

When using this product

■ Avoid contact with eyes

if pregnant or breast feeding, ask a health professional before use.

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

Product of Australia

Contains Only Natural Ingredients

Contents: 50mL (1.69 fl oz)

OBS-003

OUT BACK PAIN RELIEF

eucalyptus oil and tea tree oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69594-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
VANILLIN (UNII: CHI530446X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69594-001-01	300 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/16/2015	
2	NDC:69594-001-02	50 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/16/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/16/2015	

Labeler - Ultra Mix (Aust) Pty Ltd (752254649)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Mix (Aust) Pty Ltd		752254649	manufacture(69594-001)

Revised: 4/2016

Ultra Mix (Aust) Pty Ltd