



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	79370	TEA TREE OIL PURE ESSENTIAL OIL
ARTG entry for	Medicine Listed	
Sponsor	Le Reve Pty Ltd	
Postal Address	PO Box 6622, BAULKHAM HILLS, NSW, 2153 Australia	
ARTG Start Date	9/07/2001	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . TEA TREE OIL PURE ESSENTIAL OIL

Product Type	Single Medicine Product	Effective Date	12/07/2019
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Permitted Indications

- Traditionally used in Aromatherapy to aids/assists with recovery from illness/convalence
- Traditionally used in Aromatherapy to enhance/promote/physical endurance/capacity/stamina
- Traditionally used in Aromatherapy to helps enhance/promote general health and wellbeing
- Traditionally used in Aromatherapy to maintain/support general health and wellbeing
- Traditionally used in Aromatherapy to helps decrease/reduce/relieve symptoms of nail mild fungal infection
- Traditionally used in Aromatherapy to anti-inflammatory/relieve inflammation
- Traditionally used in Aromatherapy to demulcent/soothe irritated tissues
- Traditionally used in Aromatherapy to decrease/reduce/relieve post nasal drip
- Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of skin hives
- Traditionally used in Aromatherapy to soothes/relieves swelling/welts associated with hives
- Traditionally used in Aromatherapy to maintain/support immune system health
- Traditionally used in Aromatherapy to helps enhance/improve/promote immune system function
- Traditionally used in Aromatherapy to maintain/support healthy immune system function
- Traditionally used in Aromatherapy to maintain/support immune system to fight illness
- Traditionally used in Aromatherapy to helps stimulate a healthy immune system response
- Traditionally used in Aromatherapy to help maintain/support emotional wellbeing
- Traditionally used in Aromatherapy to maintain/support general mental wellbeing
- Traditionally used in Aromatherapy to nervine/support nervous system
- Traditionally used in Aromatherapy to support healthy emotional/mood balance
- Traditionally used in Aromatherapy to decrease/reduce/relieve vaginal discomfort
- Traditionally used in Aromatherapy to helps decrease/reduce/relieve mild vaginal itch
- Traditionally used in Aromatherapy to decongestant/relieve nasal congestion

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Traditionally used in Aromatherapy to unblock/clear nasal passages
Traditionally used in Aromatherapy to decrease/reduce/relieve mild bronchial irritation
Traditionally used in Aromatherapy to decrease/reduce/relieve bronchial mucous congestion
Traditionally used in Aromatherapy to soothe/calm the chest
Traditionally used in Aromatherapy to decrease/reduce excess chest phlegm
Traditionally used in Aromatherapy to helps decrease/reduce/relieve the severity of symptoms of common colds and flu
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of common colds and flu
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of head cold
Traditionally used in Aromatherapy to loosen chest phlegm
Traditionally used in Aromatherapy to decrease/reduce excess mucous
Traditionally used in Aromatherapy to decrease/reduce/relieve mild upper respiratory tract congestion
Traditionally used in Aromatherapy to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
Traditionally used in Aromatherapy to helps soothe respiratory tract
Traditionally used in Aromatherapy to expectorant/clear respiratory tract mucous
Traditionally used in Aromatherapy to loosen respiratory tract mucous
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of sinusitis
Traditionally used in Aromatherapy to decrease/reduce/relieve the severity of common cold symptoms
Traditionally used in Aromatherapy to relieve symptoms of mild upper respiratory tract infections
Traditionally used in Aromatherapy to helps reduce occurrence of symptoms of upper respiratory tract infections
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of common cold
Traditionally used in Aromatherapy to antitussive/cough suppressant
Traditionally used in Aromatherapy to decrease/reduce/relieve mild bronchial cough
Traditionally used in Aromatherapy to decrease/reduce/relieve cough
Traditionally used in Aromatherapy to relieve dry unproductive cough
Traditionally used in Aromatherapy to enhance/improve/promote/increase cough productivity
Traditionally used in Aromatherapy to soothe respiratory tract mucous membranes/mucous tissue
Traditionally used in Aromatherapy to helps enhance/improve nose breathing
Traditionally used in Aromatherapy to helps decrease/reduce/relieve nasal itching
Traditionally used in Aromatherapy to relieve runny/dripping nose
Traditionally used in Aromatherapy to relieve symptoms of acne
Traditionally used in Aromatherapy to decrease/reduce/relieve congested skin pores
Traditionally used in Aromatherapy to helps reduce occurrence of congested skin pores
Traditionally used in Aromatherapy to relieve minor skin eruptions
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of acne blackheads
Traditionally used in Aromatherapy to helps reduce occurrence of blackheads
Traditionally used in Aromatherapy to helps reduce occurrence of symptoms of acne
Traditionally used in Aromatherapy to decrease/reduce/relieve pimples
Traditionally used in Aromatherapy to helps reduce occurrence of pimples
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of dandruff
Traditionally used in Aromatherapy to helps reduce occurrence of symptoms of dandruff
Traditionally used in Aromatherapy to soothe skin
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of boils
Traditionally used in Aromatherapy to decrease/reduce/relieve burning/tingling associated with facial cold sores
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of mild, superficial skin fungal infections
Traditionally used in Aromatherapy to decrease/reduce/relieve skin burning/itching associated with athlete's foot/tinea
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of athlete's foot/tinea
Traditionally used in Aromatherapy to decrease/reduce/relieve skin chafing
Traditionally used in Aromatherapy to soothes/relieves heat rash
Traditionally used in Aromatherapy to soothe/relieve skin inflammation
Traditionally used in Aromatherapy to decrease/reduce/relieve skin irritation
Traditionally used in Aromatherapy to antipruritic/Relieves itchy skin
Traditionally used in Aromatherapy to helps reduce occurrence of nappy rash
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of nappy rash
Traditionally used in Aromatherapy to decrease/reduce/relieve prickly heat skin rash
Traditionally used in Aromatherapy to relieve red skin rash



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Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of medically diagnosed shingles
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of chickenpox
Traditionally used in Aromatherapy to help reduce/relieve warts
Traditionally used in Aromatherapy to soothe/relieve mild skin burn/sunburns
Traditionally used in Aromatherapy to cleanse minor skin wound/cuts/scratches/abrasions
Traditionally used in Aromatherapy to antimicrobial for minor cuts and abrasions
Traditionally used in Aromatherapy to antiseptic for minor cuts and abrasions
Traditionally used in Aromatherapy to enhance/improve healing of minor skin wound/cuts/scratches/abrasions
Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of insect bite/sting
Traditionally used in Aromatherapy to help decrease/reduce/relieve burning sensation/irritation upon urination associated with medically diagnosed cystitis
Traditionally used in Aromatherapy to help decrease/reduce/relieve symptoms of medically diagnosed cystitis

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Respiratory tract infections must be qualified by 'mild'.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must only refer to mild bronchitis.

Product presentation must not imply or refer to chronic fatigue syndrome.

Label statement: If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

Product presentation must not imply or refer to serious infections.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must only refer to medically diagnosed cystitis.

Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.

Label statement: If symptoms persist or worsen talk to your medical practitioner.

If product is indicated for skin burn, Label statement: Immediate treatment of burns should be application of cold water for ten minutes (or words to that effect).

If product is indicated for skin burn, Label statement: Only to be used for minor burns after initial first aid treatment, medical advice should be sought for serious burns.

Product presentation must only refer to 'mild' burns.

Product presentation must only refer to mild fungal infection.

Product presentation must only refer to medically diagnosed shingles.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not to be taken.

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

If symptoms persist consult your healthcare practitioner (or words to that effect).

For the treatment of burns, immediate treatment should consist of the rapid application of cold for a suitable period and the product should only be applied later [or words to that effect] the product is for the first-aid treatment of minor burns only and medical advice should be sought for the treatment of more serious burns [Or words to that effect].

Keep out of reach of children (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

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Dosage Form Liquid, multipurpose
Route of Administration Inhalation
Topical

Visual Identification

Active Ingredients

Melaleuca Oil	898 mg/mL
Equivalent: Cajuput Oil	0 mg/mL
Equivalent: cineole	26.94 mg/mL

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