



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	335610	Olive Leaf
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	2/05/2020	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

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.

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 . Olive Leaf

Product Type	Single Medicine Product	Effective Date	4/05/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Western herbal medicine to temporarily relieve mild fluid retention
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Traditionally used in Western herbal medicine to maintain/support cardiovascular system health
- Traditionally used in Western herbal medicine to maintain/support healthy cardiovascular system function
- Traditionally used in Western herbal medicine to maintain/support immune system health
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function

Indication Requirements

- Label statement: Not to be used in children under 5 years.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild fluid retention.
- Label statement: If fluid retention persists, seek medical advice (or words to that effect).
- Product presentation must not imply or refer to cardiovascular or renal conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Olea europaea leaf Extract liquid	1.067 g/mL
Equivalent: Olea europaea (Fresh)	1.067 g/mL

Other Ingredients (Excipients)

citric acid

Flavour

potassium hydroxide

potassium sorbate

purified water

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