



Australian Government

Department of Health, Disability and Ageing

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	Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020 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.		
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
		17/07/2025
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		
Product presentation must not imply or refer to serious immunological diseases.		
Product presentation must not imply or refer to cardiovascular or renal conditions.		
Label statement: If symptoms persist, talk to your health professional.		
Label statement: If fluid retention persists, seek medical advice (or words to that effect).		
Product presentation must not imply or refer to serious cardiovascular conditions.		
Label statement: Not to be used in children under 5 years.		
Product presentation must only refer to mild fluid retention.		
Standard Indications		
No Standard Indications included on Record		
Specific Indications		
No Specific Indications included on Record		
Warnings		
Contains sorbates		
Additional Product information		



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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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