



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	297951	Olive Leaf 7500
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	22/12/2017	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 7500

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/02/2021
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support general health and wellbeing

Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Maintain/support cardiovascular system health

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

Maintain/support healthy cardiovascular system function

Maintain/support immune system health

Maintain/support healthy immune system function

#### Indication Requirements

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

Label statement: Not to be used in children under 5 years.

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

Product presentation must not imply or refer to serious cardiovascular conditions.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Olea europaea leaf Extract dry concentrate standardised</b>	<b>750 mg</b>
Equivalent: Olea europaea (Dry)	7.5 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
chlorophyllin-copper complex  
croscarmellose sodium  
crospovidone  
hypromellose  
macrogol 8000  
magnesium stearate  
microcrystalline cellulose  
povidone  
silicon dioxide  
titanium dioxide

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