



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

## Public Summary

<b>Summary for ARTG Entry:</b>	283069	Macu-Guard
<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>	30/11/2016	
<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.

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 . Macu-Guard

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/01/2020
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support healthy eye function  
Maintain/support eye health  
Helps maintain/support eye macula health  
Helps maintain/support eye retina health  
Helps temporarily relieve light sensitivity  
Aids/assists eye adaption to variations in light intensity/night vision  
Maintain/support healthy eyesight/vision

#### Indication Requirements

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.  
Label statement: If symptoms persist, talk to your health professional.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>250 mg</b>
<b>copper gluconate</b>	<b>7.14 mg</b>
Equivalent: copper	1 mg
<b>d-alpha-tocopheryl acid succinate</b>	<b>165.3 mg</b>
Equivalent: d-alpha-tocopherol	200 IU
<b>Tagetes erecta flower Extract dry concentrate standardised</b>	<b>133.3 mg</b>
Equivalent: Tagetes erecta (Dry)	933 mg
<b>Vaccinium myrtillus fruit Extract dry concentrate standardised</b>	<b>100 mg</b>
Equivalent: Vaccinium myrtillus (Fresh)	10 g
<b>zeaxanthin</b>	<b>2 mg</b>
<b>zinc citrate dihydrate</b>	<b>77.9 mg</b>
Equivalent: zinc	25 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
colloidal anhydrous silica  
crospovidone  
ethylcellulose  
hypromellose  
iron oxide red  
macrogol 400  
magnesium stearate  
maltodextrin  
microcrystalline cellulose

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