



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

## Public Summary

<b>Summary for ARTG Entry:</b>	266613	Hayfever & Sinus Ease
<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>	23/12/2015	
<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.

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 . Hayfever & Sinus Ease

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	14/04/2020
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear lung-heat  
Traditionally used in Chinese medicine to clear/expel and resolve heat-phlegm  
Maintain/support general health and wellbeing  
Traditionally used in Western herbal medicine to astringent/tightens tissues  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of hayfever  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support immune system to fight illness  
Traditionally used in Western herbal medicine to decongestant/relieve nasal congestion  
Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion  
Traditionally used in Western herbal medicine to decrease/reduce excess mucous  
Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous  
Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis  
Traditionally used in Western herbal medicine to decrease/reduce/relieve cough  
Traditionally used in Western herbal medicine to enhance/improve/promote/increase cough productivity  
Traditionally used in Western herbal medicine to maintain/support healthy mucous membranes/mucous tissue of the respiratory tract  
Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract

### Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.  
Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).



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If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

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

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

Product presentation must not imply or refer to disease in any body organ.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

**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>Allium sativum bulb Extract dry concentrate</b>	<b>125 mg</b>
Equivalent: Allium sativum (Dry)	1.5 g
<b>Armoracia rusticana root Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Armoracia rusticana (Dry)	3 g
<b>ascorbic acid</b>	<b>250 mg</b>
<b>Euphrasia officinalis herb Extract dry concentrate</b>	<b>500 mg</b>
Equivalent: Euphrasia officinalis (Dry)	2 g
<b>Scutellaria baicalensis root Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Scutellaria baicalensis (Dry)	1 g

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- dl-alpha-tocopherol
- hypromellose
- iron oxide yellow
- macrogol 8000
- magnesium stearate
- microcrystalline cellulose
- povidone
- titanium dioxide

Public Summary

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