



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	266613	Hayfever & Sinus Ease
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	23/12/2015	
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 . Hayfever & Sinus Ease

Product Type	Single Medicine Product	Effective Date	14/04/2020
---------------------	-------------------------	-----------------------	------------

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
- Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract
- Traditionally used in Western herbal medicine to 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).

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

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

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.