Australian Government

Department of Health, Disability and Ageing

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 Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020

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.

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 26/09/2025

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: If symptoms persist, talk to your health professional.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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

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.

Page 1 of 2

Department of Health, Disability and Ageing

Therapeutic Goods Administration

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

© 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.