



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	269272 Lung Care
ARTG entry for	Medicine Listed
Sponsor	Herbs of Gold Pty Ltd
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia
ARTG Start Date	5/02/2016
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 . Lung Care

Product Type	Single Medicine Product	Effective Date	18/03/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Ayurvedic medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Traditionally used in Ayurvedic medicine to antispasmodic/spasmolytic
- 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 Ayurvedic medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal medicine to decrease/reduce/relieve cough
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve cough
- Traditionally used in Western herbal medicine to maintain/support lung health
- Maintain/support lung health
- Traditionally used in Western herbal medicine to lung tonic/Enhance lung health

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.
- Product presentation must not imply or refer to serious immunological diseases.
- 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 musculoskeletal or neurological conditions.
- Label statement: Not to be used in children under 5 years.

Standard Indications



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No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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

ascorbic acid	300 mg
d-alpha-tocopheryl acid succinate	30.8 mg
Equivalent: d-alpha-tocopherol	37.3 IU
Glycyrrhiza glabra root and stolon Extract dry concentrate	200 mg
Equivalent: Glycyrrhiza glabra (Dry)	1 g
Inula helenium root Extract dry concentrate	100 mg
Equivalent: Inula helenium (Dry)	1 g
Justicia adhatoda leaf Extract dry concentrate	50 mg
Equivalent: Justicia adhatoda (Dry)	500 mg
selenomethionine	60 microgram
Equivalent: selenium	25 microgram

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hydrogenated vegetable oil
hypromellose
iron oxide black
iron oxide red
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone
titanium dioxide

Public Summary

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