



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|-----------------------|
| Summary for ARTG Entry: | 329108 | Mediherb Garlic Forte |
| ARTG entry for | Medicine Listed | |
| Sponsor | Integria Healthcare Australia Pty Ltd | |
| Postal Address | PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia | |
| ARTG Start Date | 23/01/2020 | |
| 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 . Mediherb Garlic Forte

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 29/01/2021 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support general health and wellbeing

Traditionally used in Western herbal medicine to antispasmodic/spasmolytic

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu

Linked indication - Relieve runny/dripping nose

Linked indication - Relieve feelings of general malaise/general debility

Linked indication - Decrease/reduce/relieve sneezing

Linked indication - Decrease/reduce/relieve cough

Traditionally used in Western herbal medicine to decrease/reduce excess mucous

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion

Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous

Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold

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).

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to chronic fatigue syndrome.

Respiratory tract infections must be qualified by 'mild'.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
If symptoms persist, seek the advice of a healthcare professional.
For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

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

Components

1 . Formulation 1

| | |
|--------------------------------|------------------------|
| Dosage Form | Tablet, enteric coated |
| Route of Administration | Oral |

Visual Identification

Active Ingredients

| | |
|--|---------------|
| Allium sativum bulb Extract dry concentrate | 300 mg |
| Equivalent: Allium sativum (Fresh) | 3.6 g |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
carmellose sodium
colloidal anhydrous silica
dl-alpha-tocopherol
ethylcellulose
Garlic Bulb Powder
magnesium stearate
medium chain triglycerides
microcrystalline cellulose
oleic acid
polydextrose
purified talc
purified water
sodium starch glycollate
strong ammonia solution

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