



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|----------------|
| Summary for ARTG Entry: | 201349 | MediHerb ResCo |
| 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 | 26/09/2012 | |
| 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 ResCo

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 4/03/2021 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration

Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation

Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues

Traditionally used in Western herbal medicine to antispasmodic/spasmolytic

Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion

Traditionally used in Western herbal medicine to decrease/reduce excess chest phlegm

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 antitussive/cough suppressant

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough

Traditionally used in Western herbal medicine to decrease/reduce/relieve cough

Traditionally used in Western herbal medicine to maintain/support 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.

Product presentation must only refer to mild bronchitis.

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

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

For practitioner dispensing only.



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Do not use if pregnant or likely to become pregnant (or words to that effect)

Use in children under 12 years is not recommended.

Do not use while breastfeeding.

If symptoms persist, seek the advice of a healthcare professional.

If symptoms persist consult your healthcare practitioner (or words to that effect).

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

| | |
|--|-----------------------|
| Euphorbia hirta herb Extract liquid | 560 microlitre |
| Equivalent: Euphorbia hirta (Dry) | 280 mg |
| Fennel Oil | 12 mg |
| Glycyrrhiza glabra root Extract dry concentrate | 142.9 mg |
| Equivalent: Glycyrrhiza glabra (Dry) | 500 mg |
| Grindelia camporum herb Extract liquid | 560 microlitre |
| Equivalent: Grindelia camporum (Dry) | 280 mg |
| Thyme Oil | 12 mg |
| Verbascum thapsus leaf Extract liquid | 940 microlitre |
| Equivalent: Verbascum thapsus (Dry) | 470 mg |
| Zingiber officinale rhizome Extract liquid | 360 microlitre |
| Equivalent: Zingiber officinale (Dry) | 180 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
glucose monohydrate
hypromellose
magnesium stearate
microcrystalline cellulose
sodium starch glycollate

Public Summary

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