## **Australian Government**

## **Department of Health**

## Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 386391 MediHerb Vira-Immune Complex

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 29/03/2022
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 Vira-Immune Complex

Product Type Single Medicine Product Effective Date 29/03/2022

## Permitted Indications

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

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 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

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 forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must only refer to mild bronchitis.

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 symptoms persist, seek the advice of a healthcare professional.

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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

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For practitioner dispensing only.

St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.

Not recommended for use by pregnant and lactating women (or words to that effect).

### **Additional Product information**

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Pack Size Poison Schedule

### Components

### 1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

### **Active Ingredients**

-		
Glycyrrhiza glabra root Extract dry concentrate	241.7 mg	
Equivalent: Glycyrrhiza glabra (Dry)	2.9 g	
Hypericum perforatum herb top flowering Extract dry concentrate	225 mg	
Equivalent: Hypericum perforatum (Dry)	1.35 g	
Thuja occidentalis leaf Extract liquid	1000 microlitre	
Equivalent: Thuja occidentalis (Dry)	200 mg	

### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica croscarmellose sodium

hypromellose

magnesium stearate

microcrystalline cellulose

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