

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	287102	MediHerb Vira-Immune Complex
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthc	are Australia Pty Ltd
Postal Address	PO Box 4854, E Australia	EIGHT MILE PLAINS, QLD, 4113
ARTG Start Date	24/03/2017	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicine	S
Constitution of		

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	20/08/2021				
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 Require	ments						
Product presentation	on must not imply or refer to serious forms	of respiratory disorders/diseases, such	n 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).							
Label statement: If symptoms persist, talk to your health professional.							
Product presentation	on must only refer to mild bronchitis.						
Product presentation	on must not imply or refer to serious muscu	loskeletal or neurological conditions.					
Standard Indicatio	ns						

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not use if pregnant or likely to become pregnant (or words to that effect) Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

For practitioner dispensing only.

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

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

Additional Product information

Pack Size/Poison information	on					
Pack Size		Poison Schedule				
Components						
1. Formulation 1						
Dosage Form	Tablet, film coated					
Route of Administration	Oral					
Visual Identification						
Active Ingredients						
Glycyrrhiza glabra rhizom	e Extract dry concentrate		166.62 mg			
Equivalent: Glycyrrhiza gla	abra (Dry)		2.916 g			
Hypericum perforatum her	rb top flowering Extract dry concentrate		225 mg			
Equivalent: Hypericum pe	rforatum (Dry)		1.35 g			
Thuja occidentalis leaf Ex	tract liquid		1000 microlitre			
Equivalent: Thuja occiden	talis (Dry)		200 mg			
Other Ingredients (Excipie	ents)					
calcium hydrogen phosph	calcium hydrogen phosphate dihydrate					
colloidal anhydrous silica	colloidal anhydrous silica					
croscarmellose sodium						
dextrin						
hypromellose						
magnesium stearate						
maltodextrin						
microcrystalline cellulose sodium starch glycollate						
socium startin grycollate						

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