

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	394433	MediHerb Artemisia Annua Forte	
ARTG entry for	Medicine Listed		
Sponsor	Integria Healthcare Australia Pty Ltd		
Postal Address	PO Box 4854, E Australia	IGHT MILE PLAINS, QLD, 4113	
ARTG Start Date	24/08/2022		
Product Category	Medicine		
Status	Active		
Approval Area	Listed Medicines	6	
Canditiana			

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 Artemisia Annua Forte Product Type Single Medicine Product Effective Date 24/08/2022

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Traditionally used in Chinese medicine to clear/cool/drain/purge/asthenic-heat/deficiency-heat

Traditionally used in Chinese medicine to clear/disperse/expel/dissipate/cool blood-heat

Traditionally used in Chinese medicine to dispel/expel/disperse/clear internal/endogenous heat

Traditionally used in Chinese medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Indication Requirements

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

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

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

Label statement: Not to be used in children under 5 years.

Standard Indications

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)

For practitioner dispensing only.

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

Additional Product information

Pack Size/Poison information

Page 1 of 2

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Produced at 06.01.2023 at 05:12:30 AEDT



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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					
Artemisia annua herb Extract dry concentrate			266.66 mg		
Equivalent: Artemisia annua (Dry)			8 g		
Other Ingredients (Excipients)					
calcium hydrogen phosphate dihydrate					
colloidal anhydrous silica					
croscarmellose sodium					
hypromellose					
magnesium stearate					
microcrystalline cellulose					

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