

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

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Summary for ARTG Entry:	292833	MediHerb PCO Support
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthca	are Australia Pty Ltd
Postal Address	PO Box 4854, E Australia	IGHT MILE PLAINS, QLD, 4113
ARTG Start Date	15/08/2017	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	3
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 PCO	1 . MediHerb PCO Support						
Product Type	Single Medicine Product	Effective Date	2/03/2021				
Permitted Indications							
Antioxidant/Reduce free	radicals formed in the body						
Helps reduce/decrease fi	ee radical damage to body cells						
Maintain/support general health and wellbeing							
Anti-inflammatory/relieve	inflammation						
Indication Requirement	S						
Label statement: If symp	toms persist, talk to your health professio	onal.					
Standard Indications							
No Standard Indications	included on Record						
Specific Indications							
No Specific Indications in	cluded on Record						
Warnings							
If symptoms persist cons	ult your healthcare practitioner (or words	to that effect).					
For practitioner dispensir	ig only.						
St John's Wort affects the	e way many prescription medicines work,	including the oral contraceptive pi	II. Consult your doctor.				
Additional Product info	rmation						
Pack Size/Poison inform	nation						
Pack Size		Poison Schedule					
Components							
1. Formulation 1							
Dosage Form	Tablet, film coated						
Route of Administrati	on _{Oral}						
Visual Identification							
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	Active	Ingredients
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Cinnamomum verum stem bark outer Extract dry concentrate	62.5 mg	
Equivalent: Cinnamomum verum (Dry)	750 mg	
Glycyrrhiza glabra root Extract dry concentrate standardised	107.2 mg	
Equivalent: Glycyrrhiza glabra (Dry)	750 mg	
Hypericum perforatum herb top flowering Extract dry concentrate standardised	125 mg	
Equivalent: Hypericum perforatum (Dry)	750 mg	
Paeonia lactiflora root Extract dry concentrate	187.5 mg	
Equivalent: Paeonia lactiflora (Dry)	750 mg	
Other Ingredients (Excipients)		

colloidal anhydrous silica crospovidone dextrin hypromellose liquid glucose magnesium stearate maltodextrin microcrystalline cellulose sodium starch glycollate

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