

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

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Summary for ARTG Entry:	172181	METAGENICS ADAPTAN	
ARTG entry for	Medicine Listed		
Sponsor	Metagenics (Aust) Pty Ltd		
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia		
ARTG Start Date	10/06/2010		
Product Category	Medicine		
Status	Active		
Approval Area	Listed Medicines		
Conditions			

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. METAGENIC	SADAPIAN			
Product Type	Single Medicine Product	Effective Date	2/07/2020	
Permitted Indication	IS			
Traditionally used in	Chinese medicine to adaptogen/Help bod	y adapt to stress		
Aids/assists the body	to cope with environmental stress			
Support healthy stres	s response in the body			
Traditionally used in	Western herbal medicine to decrease/red	uce/relieve restlessness/excess nerv	vous energy	
Traditionally used in	Chinese medicine to decrease/reduce/reli	eve restlessness/excess nervous en	lergy	
Traditionally used in	Chinese medicine to decrease/reduce/reli	eve symptoms of stress		
	Relieve weariness/tiredness/fatigue/feelin Decrease/reduce/relieve nervous tension			
Traditionally used in	Chinese medicine to decrease/reduce/reli	eve symptoms of stress		
Traditionally used in	Western herbal medicine to decrease/red	uce/relieve symptoms of stress		
	Relieve weariness/tiredness/fatigue/feelin Decrease/reduce/relieve nervous tension			
Traditionally used in	Western herbal medicine to decrease/red	uce/relieve symptoms of stress		
Traditionally used in	Western herbal medicine to decrease/red	uce/relieve nervous tension/unrest		
Traditionally used in	Western herbal medicine to decrease/red	uce/relieve symptoms of mild anxiety	/	
	Relieve weariness/tiredness/fatigue/feelin Decrease/reduce/relieve nervous tension			
Traditionally used in	Western herbal medicine to decrease/red	uce/relieve symptoms of mild anxiety	/	
Traditionally used in	Chinese medicine to decrease/reduce/reli	eve symptoms of mild anxiety		
	Relieve weariness/tiredness/fatigue/feelin Decrease/reduce/relieve nervous tension			
Traditionally used in	Western herbal medicine to maintain/supp	oort nervous system health		
Indication Requirem	nents			
Label statement: If s	ymptoms persist, talk to your health profe	ssional.		
Product presentation	n must not imply or refer to mental illnesse	es, disorders or conditions.		
Product presentation	must only refer to mild anxiety.			
Product presentation	n must not imply or refer to chronic fatigue	syndrome.		

Standard Indications

No Standard Indications included on Record

Specific Indications

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No Specific Indications included on Record

Warnings

'Contains gluten (or words to that effect)'

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	
Avena sativa herb Extract dry concentrate	100 mg
Equivalent: Avena sativa (Dry)	1 g
Lavandula angustifolia herb Extract dry concentrate	250 mg
Equivalent: Lavandula angustifolia (Dry)	1 g
Panax quinquefolius root Extract dry concentrate	300 mg
Equivalent: Panax quinquefolius (Dry)	1.5 g
Rehmannia glutinosa root Extract dry concentrate	416.667 mg
Equivalent: Rehmannia glutinosa (Dry)	2.5 g
Other Ingredients (Excipients)	
croscarmellose sodium	
hyprolose	
macrogol 8000	
magnesium stearate	
microcrystalline cellulose	
silicon dioxide	
stearic acid	

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