



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	373379	THYROCALM
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	24/08/2021	
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 . THYROCALM

Product Type	Single Medicine Product	Effective Date	24/08/2021
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Permitted Indications

Traditionally used in Chinese medicine to dispel/expel/disperse/clear fire in/of Heart Fire pattern

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish heart-yin

Maintain/support general health and wellbeing

Relieve irritability

Traditionally used in Chinese medicine to relieve irritability

Traditionally used in Western herbal medicine to soothe/calm nerves

Decrease/reduce/relieve nervous tension/unrest

Traditionally used in Western herbal medicine to nervine/support nervous system

Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness

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 heart disease.

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components



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1 . Formulation 1

Dosage Form Tablet, film coated
Route of Administration Oral

Visual Identification

Active Ingredients

Melissa officinalis leaf Extract dry concentrate	250 mg
Equivalent: Melissa officinalis (Dry)	1 g
Phyllanthus emblica fruit Extract dry concentrate	100 mg
Equivalent: Phyllanthus emblica (Dry)	500 mg
Prunella vulgaris flower Extract dry concentrate	150 mg
Equivalent: Prunella vulgaris (Dry)	1.5 g
Rehmannia glutinosa root Extract dry concentrate	300 mg
Equivalent: Rehmannia glutinosa (Dry)	3 g

Other Ingredients (Excipients)

colloidal anhydrous silica
croscarmellose sodium
glycerol
hypromellose
magnesium stearate
microcrystalline cellulose

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