



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	115858	THYROCALM
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	21/01/2005	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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	28/02/2020
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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.

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

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

Product presentation must not imply or refer to heart disease.

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).

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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

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	500 mg
Equivalent: Rehmannia glutinosa (Dry)	3 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
carrageenan
croscarmellose sodium
hypromellose
macrogol 8000
magnesium stearate
microcrystalline cellulose
silicon dioxide
soy polysaccharide
stearic acid

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