



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	359716	Metagenics Thyrobalance
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	5/04/2021 11:00:00 PM	
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.

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 . Metagenics Thyrobalance

Product Type	Single Medicine Product	Effective Date	6/04/2021
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Permitted Indications

- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Chinese medicine to maintain/support energy levels
- Traditionally used in Ayurvedic medicine to maintain/support energy levels
- Maintain/support body metabolism/metabolic rate
- Maintain/support energy production
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production
- Traditionally used in Ayurvedic medicine to support healthy stress response in the body
- Support healthy stress response in the body
- Traditionally used in Ayurvedic medicine to nerve tonic
- Traditionally used in Ayurvedic medicine to maintain/support nervous system health

Indication Requirements

- If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- Product presentation must not imply or refer to any thyroid related diseases.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for

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men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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

d-alpha-tocopheryl acid succinate	110.34 mg
Equivalent: d-alpha-tocopherol	133.51 IU
Lycium barbarum fruit Extract dry concentrate	250 mg
Equivalent: Lycium barbarum (Dry)	3 g
nicotinamide	100 mg
potassium iodide	91.56 microgram
Equivalent: iodine	70 microgram
retinol palmitate	.2404 mg
Equivalent: vitamin A	.1297 mg
riboflavin	5 mg
Rosmarinus officinalis leaf Extract dry concentrate	125 mg
Equivalent: Rosmarinus officinalis (Dry)	500 mg
selenomethionine	93.75 microgram
Equivalent: selenium	37.5 microgram
Withania somnifera root Extract dry concentrate	150 mg
Equivalent: Withania somnifera (Dry)	1.5 g
zinc sulfate monohydrate	16.48 mg
Equivalent: zinc	6 mg
Zingiber officinale rhizome Extract dry concentrate	62.5 mg
Equivalent: Zingiber officinale (Dry)	1 g

Other Ingredients (Excipients)

- calcium hydrogen phosphate
- croscarmellose sodium
- dl-alpha-tocopherol
- ethylcellulose
- Gelatin
- hypromellose
- macrogol 8000
- magnesium stearate
- maize starch
- microcrystalline cellulose
- silicon dioxide
- stearic acid

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