



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	392398	Metabolism & Thermogenic AM Formula
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 380, Peregian Beach, QLD, 4573 Australia	
ARTG Start Date	18/07/2022	
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 . Metabolism & Thermogenic AM Formula

Product Type	Single Medicine Product	Effective Date	18/07/2022
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Permitted Indications

- Maintain/support body metabolism/metabolic rate
- Traditionally used in Western herbal medicine to maintain/support physical endurance/capacity/stamina
- Maintain/support heat/energy production/thermogenesis
- Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function
- Traditionally used in Western herbal medicine to maintain/support healthy thyroid gland function
- Traditionally used in Western herbal medicine to maintain/support thyroid gland health
- Traditionally used in Ayurvedic medicine to decrease/reduce carbohydrate cravings
- Traditionally used in Ayurvedic medicine to aid/assist/helps in the management of sugar cravings
- Traditionally used in Ayurvedic medicine to reduce/decrease/suppress hunger/appetite
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress

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 mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to any thyroid related diseases.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to eating disorders.
- Product presentation must not imply or refer to any adrenal related diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- Adults only.
- Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant



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coffee contains approximately 80mg of caffeine.

Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Camellia sinensis leaf Extract dry concentrate standardised	106.67 mg
Equivalent: Camellia sinensis (Dry)	2.67 g
Capsicum annum fruit Extract dry concentrate	16.67 mg
Equivalent: Capsicum annum (Dry)	333.3 mg
Fucus vesiculosus whole plant Extract dry concentrate	75 mg
Equivalent: Fucus vesiculosus (Dry)	750 mg
Glycyrrhiza glabra rhizome Extract dry concentrate	64.1 mg
Equivalent: Glycyrrhiza glabra (Dry)	833.33 mg
Gymnema sylvestre leaf Extract dry concentrate	100 mg
Equivalent: Gymnema sylvestre (Dry)	2 g
Panax ginseng root Extract dry concentrate	10 mg
Equivalent: Panax ginseng (Dry)	100 mg
Plectranthus barbatus root Extract dry concentrate	44.44 mg
Equivalent: Plectranthus barbatus (Dry)	2 g

Other Ingredients (Excipients)

ascorbyl palmitate

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

maltodextrin

microcrystalline cellulose

potable water

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