



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	392398	Metabolism & Thermogenic AM Formula
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	NRC Nutrition Pty Ltd	
<b>Postal Address</b>	PO Box 380, Peregian Beach, QLD, 4573 Australia	
<b>ARTG Start Date</b>	18/07/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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
--------------	-------------------------	----------------	------------

### 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

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

### 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

Public Summary



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

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

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

#### Other Ingredients (Excipients)

ascorbyl palmitate

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

maltodextrin

microcrystalline cellulose

potable water

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary