



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	331102	METAGENICS THERMO BURN
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	13/03/2020	
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 . METAGENICS THERMO BURN

Product Type	Single Medicine Product	Effective Date	13/03/2020
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Permitted Indications

Helps enhance/promote calorie burning
Maintain/support calorie burning
Helps improve/promote body metabolism/metabolic rate
Maintain/support body metabolism/metabolic rate
Helps enhance/promote heat/energy production/thermogenesis
Maintain/support heat/energy production/thermogenesis
Reduce/decrease/suppress hunger/appetite
Helps regulate appetite

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 eating disorders.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

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

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 coffee contains approximately 80mg of caffeine.

Caffeine interacts with the liver enzyme CYP1A2. Consult your health professional before taking with other medicines' (or words to that effect).



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Limit the use of caffeine-containing products (including tea and coffee) when taking this product.
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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Camellia sinensis leaf Extract dry concentrate standardised	450 mg
Equivalent: Camellia sinensis (Dry)	11.25 g
Capsicum annum fruit Extract dry concentrate	35 mg
Equivalent: Capsicum annum (Dry)	1.4 g
Theobroma cacao seed Extract dry concentrate	140 mg
Equivalent: Theobroma cacao (Dry)	630 mg

Other Ingredients (Excipients)

croscarmellose sodium
hypromellose
hypromellose
macrogol 8000
magnesium stearate
microcrystalline cellulose
silicon dioxide

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