



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	256014	Weight Management Diet Drops
ARTG entry for	Medicine Listed	
Sponsor	Eagle Supreme Health Pty Ltd ATF Eagle Supreme Family Trust	
Postal Address	PO Box 131, WANNEROO, WA, 6946 Australia	
ARTG Start Date	18/08/2015	
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 . Weight Management Diet Drops

Product Type	Single Medicine Product	Effective Date	25/02/2021
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Permitted Indications

Maintain/support heat/energy production/thermogenesis
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Indication Requirements

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Contains ethanol or contains alcohol.

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Oral Liquid
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Route of Administration	Oral
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Visual Identification

Active Ingredients

alanine	14.5 mg/mL
Camellia sinensis leaf Extract dry concentrate	7.25 mg/mL
Equivalent: Camellia sinensis (Dry)	72.5 mg/mL
glutamine	14.5 mg/mL
histidine	14.5 mg/mL
leucine	7.25 mg/mL
levocarnitine	14.5 mg/mL
nicotinic acid	10 mg/mL
ornithine monohydrochloride	14.5 mg/mL
Rhodiola rosea root Extract dry concentrate	9.06 mg/mL
Equivalent: Rhodiola rosea (Dry)	72.48 mg/mL
threonine	14.5 mg/mL

Other Ingredients (Excipients)

- ethanol
- potassium sorbate
- purified water
- vanillin

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