



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	409943	De-Stress Easy
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	2/06/2023	
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 . De-Stress Easy

Product Type	Single Medicine Product	Effective Date	2/06/2023
--------------	-------------------------	----------------	-----------

Permitted Indications

- Traditionally used in European herbal medicine to maintain/support energy levels
- Maintain/support energy levels
- Maintain/support energy production
- Traditionally used in European herbal medicine to maintain/support physical endurance/capacity/stamina
- Maintain/support physical endurance/capacity/stamina
- Traditionally used in European herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in European herbal medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral) within normal range
- Traditionally used in European herbal medicine to adaptogen/Help body adapt to stress
- Support healthy body stress recovery
- Traditionally used in European herbal medicine to support healthy body stress recovery
- Support healthy stress response in the body
- Traditionally used in European herbal medicine to support healthy stress response in the body
- Traditionally used in European herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Maintain/support mental endurance/stamina
- Maintain/support cognitive function/mental function
- Maintain/support memory/mental recall
- Aid/assist/helps synthesis of neurotransmitters
- Traditionally used in European herbal medicine to maintain/support nervous system health
- Maintain/support nervous system health
- Maintain/support nervous system function

Public Summary



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Indication Requirements

Product presentation must not imply or refer to serious immunological 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.
 Product presentation must only refer to mild anxiety.
 Label statement: If symptoms persist, talk to your health professional.
 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.
 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).
 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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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**

Components

1 . Formulation 1

Dosage Form Spray
Route of Administration Oral

Visual Identification

Active Ingredients

Camellia sinensis leaf Extract dry concentrate	1.15 mg/mL
Equivalent: Camellia sinensis (Dry)	184 mg/mL
pyridoxine hydrochloride	1.4 mg/mL
Equivalent: pyridoxine	1.15 mg/mL
Rhodiola rosea root Extract dry concentrate	27.6 mg/mL
Equivalent: Rhodiola rosea (Dry)	220.8 mg/mL

Other Ingredients (Excipients)

dextrin
 Flavour
 glycerol
 malic acid
 potassium sorbate
 purified water
 Siraitia grosvenorii

Public Summary

© 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>.