



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	357356	He Focus & De-Stress Formula
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	23/03/2021	
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 . He Focus & De-Stress Formula

Product Type	Single Medicine Product	Effective Date	9/04/2021
--------------	-------------------------	----------------	-----------

Permitted Indications

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Enhance/promote energy levels
- Traditionally used in Ayurvedic medicine to enhance/promote energy levels
- Maintain/support energy levels
- Helps convert (state food) into energy
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Western herbal medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Traditionally used in Western herbal medicine to relieve feelings of general malaise/general debility
- Traditionally used in Ayurvedic medicine to maintain/support vitality
- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support body electrolyte balance
- Maintain/support healthy growth and development
- Helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support bone health
- Aid/assist healthy red blood cell production
- Maintain/support immune system health
- Maintain/support muscle function
- Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase physical/exercise performance
- Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral) within normal range
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

- Traditionally used in Ayurvedic medicine to enhance/promote body adaptation to stress
- Traditionally used in Ayurvedic medicine to support healthy stress response in the body
- Traditionally used in Western herbal medicine to decrease/reduce mental/cognitive fatigue
- Traditionally used in Western herbal medicine to maintain/support mental concentration/focus/clarity
- Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase cognitive performance
- Traditionally used in Western herbal medicine to maintain/support mental endurance/stamina
- Traditionally used in Western herbal medicine to maintain/support cognitive function/mental function
- Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to chronic fatigue syndrome.

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).

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to serious cardiovascular conditions.

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 Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not take while on warfarin therapy without medical advice.

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

calcium folinate	.2604 mg
Equivalent: folic acid	.2 mg
calcium pantothenate	27.17 mg
Equivalent: pantothenic acid	25 mg
Eleutherococcus senticosus root Extract dry concentrate	100 mg
Equivalent: Eleutherococcus senticosus (Dry)	1000 mg
Ganoderma lucidum fruiting body Powder	50 mg
Grifola frondosa fruiting body Powder	50 mg
magnesium citrate	162.41 mg
Equivalent: magnesium	26.25 mg

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

magnesium glycinat	218.75 mg
Equivalent: magnesium	26.25 mg
mecobalamin (co-methylcobalamin)	.0025 mg
nicotinamide	7.5 mg
nicotinic acid	2.5 mg
pyridoxal 5-phosphate	3.65 mg
Equivalent: pyridoxine	2.5 mg
riboflavin sodium phosphate	3.42 mg
Equivalent: riboflavin	2.5 mg
thiamine hydrochloride	15.89 mg
Equivalent: thiamine	12.5 mg
Withania somnifera root Extract dry concentrate	75 mg
Equivalent: Withania somnifera (Dry)	1.5 g
Wolfiporia cocos fruiting body Powder	50 mg

Other Ingredients (Excipients)

Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
magnesium stearate
microcrystalline cellulose

© 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