



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	314808 Herbal Vitality
ARTG entry for	Medicine Listed
Sponsor	Lyndelen Pty Ltd T/A The Herbal Extract Co of Australia
Postal Address	PO Box 107, PANANIA, NSW, 2213 Australia
ARTG Start Date	26/02/2019
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

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 . Herbal Vitality

Product Type	Single Medicine Product	Effective Date	26/02/2019
--------------	-------------------------	----------------	------------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Enhance/promote/physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Western herbal medicine to nutritive tonic
- Helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Maintain/support cardiovascular system health
- Traditionally used in Western herbal medicine to helps maintain/support healthy heart function
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Helps enhance/promote healthy digestive system function
- Maintain/support immune system health
- Helps enhance/improve/promote/increase physical/exercise performance
- Traditionally used in Chinese medicine to adaptogen/Help body adapt to stress
- Aids/assists the body to cope with environmental stress
- Enhance/promote body adaptation to stress
- Support healthy body stress recovery
- Support healthy stress response in the body
- Support healthy stress response in the body
- Decrease/reduce/relieve symptoms of stress
- Enhance/improve/promote/increase cognitive performance
- Maintain/support cognitive function/mental function

Indication Requirements

- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to serious immunological diseases.

Public Summary



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.
 'Contains gluten (or words to that effect)'

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Avena sativa seed Extract liquid	35.5 mg/mL
Equivalent: Avena sativa (Dry)	35.5 mg/mL
Cinnamomum verum stem bark outer Extract liquid	7.1 mg/mL
Equivalent: Cinnamomum verum (Dry)	7.1 mg/mL
Crataegus monogyna fruit Extract liquid	71.1 mg/mL
Equivalent: Crataegus monogyna (Dry)	71.1 mg/mL
Eleutherococcus senticosus root Extract liquid	53.3 mg/mL
Equivalent: Eleutherococcus senticosus (Dry)	53.3 mg/mL
Equisetum arvense herb Extract liquid	35.5 mg/mL
Equivalent: Equisetum arvense (Dry)	35.5 mg/mL
Euphrasia officinalis herb Extract liquid	71.1 mg/mL
Equivalent: Euphrasia officinalis (Dry)	71.1 mg/mL
Petroselinum crispum root Extract liquid	88.8 mg/mL
Equivalent: Petroselinum crispum (Dry)	88.8 mg/mL
Rehmannia glutinosa root Extract liquid	71.1 mg/mL
Equivalent: Rehmannia glutinosa (Dry)	71.1 mg/mL
Rosmarinus officinalis leaf Extract liquid	7.1 mg/mL
Equivalent: Rosmarinus officinalis (Dry)	7.1 mg/mL
Syzygium aromaticum flower bud Extract liquid	1.8 mg/mL
Equivalent: Syzygium aromaticum (Dry)	1.8 mg/mL
Taraxacum officinale root Extract liquid	71.1 mg/mL
Equivalent: Taraxacum officinale (Dry)	71.1 mg/mL
Trifolium pratense flower Extract liquid	71.1 mg/mL
Equivalent: Trifolium pratense (Dry)	71.1 mg/mL
Urtica dioica leaf Extract liquid	88.8 mg/mL
Equivalent: Urtica dioica (Dry)	88.8 mg/mL
Vaccinium myrtillus fruit Extract liquid	10.7 mg/mL
Equivalent: Vaccinium myrtillus (Dry)	10.7 mg/mL

Other Ingredients (Excipients)

Anise Oil

Public Summary



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

glycerol

Peppermint Oil

© 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