Public Summary

Summary for ARTG Entry: 235127 Protandim

ARTG entry for	Medicine Listed
Sponsor	LifeVantage Australia Pty Ltd
Postal Address	25 Burton Street, Glebe, NSW, 2037 Australia
ARTG Start Date	17/03/2015
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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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. Protandim

Product Type Single Medicine Product **Effective date** 6/01/2018

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.

Help reduce effects of mild anxiety and nervous tension. [Warning S required]

Relief of indigestion. [Warning S required]

Liver tonic. Relief of indigestion. [Warning S required]

Aids digestion.

Helps maintain healthy digestive function.

Formula to support the liver.

Liver tonic. Helps maintain healthy digestive function.

May assist in the management of non-specific dyspepsia. [Warning S required]

Liver tonic.

Liver formula.

Beneficial during times of stress. [Warning S required]

Liver tonic. Aids digestion.

Specific Indications

Protection against oxidative stress. Essential for normal metabolism and protect cells against oxidative stress. Antioxidants help to reduce effects caused by free radical scavengers. Assists in maintaining peak effort. Helps body adapt to physically and mentally draining circumstances. Helps maintain normal vitality/energy. Helps support/maintain healthy immune function. Relief of stress and mild anxiety. Supports/maintains the body's normal ability to cope during times of stress. Helps release the feelings of fatigue caused by stress.

Warnings

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.

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

Bacopa monnieri	**150 mg**
Equivalent: Bacopa monnieri (Dry)	3 g
Camellia sinensis	**75 mg**
Equivalent: Camellia sinensis (Dry)	1.875 g
Curcuma longa	**75 mg**
Equivalent: Curcuma longa (Dry)	1.95 g
Silybum marianum	**225 mg**
Equivalent: Silybum marianum (Dry)	5.62 g
Withania somnifera	**150 mg**
Equivalent: Withania somnifera (Dry)	975 mg

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