Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	201419	METAGENICS STRESSAN
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	27/09/2012	
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 . METAGENICS STRESSAN

Product Type Single Medicine Product **Effective Date** 10/12/2019

Permitted Indications

Traditionally used in Chinese medicine to support healthy stress response in the body

Traditionally used in Chinese medicine to relieve irritability

Traditionally used in Chinese medicine to calms the mind

Traditionally used in Chinese medicine to aid/assist/helps mind relaxation

Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit

Traditionally used in Chinese medicine to soothe/calm nerves

Traditionally used in Chinese medicine to calmative/nervous system relaxant

Indication Requirements

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

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bupleurum falcatum root Extract dry concentrate	**83.4 mg**
Equivalent: Bupleurum falcatum (Dry)	834 mg
Cinnamomum cassia twig Extract dry concentrate	**50 mg**
Equivalent: Cinnamomum cassia (Dry)	500 mg
hydroxyapatite	**46 mg**
Panax ginseng root and rhizome Extract dry concentrate	**41.7 mg**
Equivalent: Panax ginseng (Dry)	417 mg
Pinellia ternata rhizome Extract dry concentrate	**66.7 mg**
Equivalent: Pinellia ternata (Dry)	667 mg
Scutellaria baicalensis root Extract dry concentrate	**41.7 mg**
Equivalent: Scutellaria baicalensis (Dry)	417 mg
Uncaria rhyncophylla stem Extract dry concentrate	**66 mg**
Equivalent: Uncaria rhyncophylla (Dry)	660 mg
Wolfiporia cocos fruiting body Extract dry concentrate	**50 mg**
Equivalent: Wolfiporia cocos (Dry)	500 mg
Zingiber officinale rhizome Extract dry concentrate	**16.7 mg**
Equivalent: Zingiber officinale (Fresh)	167 mg
Ziziphus jujuba fruit Extract dry concentrate	**41.8 mg**
Equivalent: Ziziphus jujuba (Dry)	418 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium stearate
potable water
potassium acetate

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