Public Summary

Summary for ARTG Entry:	192923 METAGENICS NEUROLIFT
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	12/12/2011
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.

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 NEUROLIFT

Product Type	Single Medicine Product	**Effective Date**	3/07/2020

Permitted Indications

Maintain/support general health and wellbeing

Maintain/support healthy thyroid gland function

Aid/assist thyroid hormone production

Enhance/promote body adaptation to stress

Support healthy stress response in the body

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
- Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
- Linked indication - Decrease/reduce mental/cognitive fatigue

Decrease/reduce/relieve symptoms of stress
- Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
- Linked indication - Maintain/support mental concentration/focus/clarity
- Linked indication - Decrease/reduce mental/cognitive fatigue

Support healthy emotional/mood balance

Indication Requirements

Product presentation must not imply or refer to any thyroid related 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.

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

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

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect).

St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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

ademetionine disulfate tosylate	**98.04 mg**
Equivalent: (S)-S-adenosylmethionine	50 mg
calcium folinate	**270.3 microgram**
Equivalent: folinic acid	250 microgram
colecalciferol	**.005 mg**
Hypericum perforatum herb Extract dry concentrate standardised	**450 mg**
Equivalent: Hypericum perforatum (Dry)	1.935 g
Plectranthus barbatus root Extract dry concentrate	**16.67 mg**
Equivalent: Plectranthus barbatus (Dry)	500 mg
potassium iodide	**98 microgram**
Equivalent: iodine	75 microgram
Rhodiola rosea root Extract dry concentrate	**36 mg**
Equivalent: Rhodiola rosea (Dry)	630 mg
selenomethionine	**125 microgram**
Equivalent: selenium	50 microgram
Withania somnifera root Extract dry concentrate	**150 mg**
Equivalent: Withania somnifera (Dry)	1.5 g

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
calcium phosphate
calcium stearate
croscarmellose sodium
dl-alpha-tocopherol
fractionated coconut oil
hyprolose
macrogol 8000
maize starch
microcrystalline cellulose
potable water
silicon dioxide
stearic acid
sucrose

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