

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

| , | | | |
|-------------------------|---|--------------------|--|
| Summary for ARTG Entry: | 172181 | METAGENICS ADAPTAN | |
| ARTG entry for | Medicine Listed | | |
| Sponsor | Metagenics (Aust) Pty Ltd | | |
| Postal Address | PO Box 675, VIRGINIA BC, QLD, 4014 Australia | | |
| ARTG Start Date | 10/06/2010 | | |
| 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. METAGENIC | SADAPIAN | | | |
|-----------------------|---|--------------------------------------|-------------|--|
| Product Type | Single Medicine Product | Effective Date | 2/07/2020 | |
| Permitted Indication | IS | | | |
| Traditionally used in | Chinese medicine to adaptogen/Help bod | y adapt to stress | | |
| Aids/assists the body | to cope with environmental stress | | | |
| Support healthy stres | s response in the body | | | |
| Traditionally used in | Western herbal medicine to decrease/red | uce/relieve restlessness/excess nerv | vous energy | |
| Traditionally used in | Chinese medicine to decrease/reduce/reli | eve restlessness/excess nervous en | lergy | |
| Traditionally used in | Chinese medicine to decrease/reduce/reli | eve symptoms of stress | | |
| | Relieve weariness/tiredness/fatigue/feelin Decrease/reduce/relieve nervous tension | | | |
| Traditionally used in | Chinese medicine to decrease/reduce/reli | eve symptoms of stress | | |
| Traditionally used in | Western herbal medicine to decrease/red | uce/relieve symptoms of stress | | |
| | Relieve weariness/tiredness/fatigue/feelin Decrease/reduce/relieve nervous tension | | | |
| Traditionally used in | Western herbal medicine to decrease/red | uce/relieve symptoms of stress | | |
| Traditionally used in | Western herbal medicine to decrease/red | uce/relieve nervous tension/unrest | | |
| Traditionally used in | Western herbal medicine to decrease/red | uce/relieve symptoms of mild anxiety | / | |
| | Relieve weariness/tiredness/fatigue/feelin Decrease/reduce/relieve nervous tension | | | |
| Traditionally used in | Western herbal medicine to decrease/red | uce/relieve symptoms of mild anxiety | / | |
| Traditionally used in | Chinese medicine to decrease/reduce/reli | eve symptoms of mild anxiety | | |
| | Relieve weariness/tiredness/fatigue/feelin Decrease/reduce/relieve nervous tension | | | |
| Traditionally used in | Western herbal medicine to maintain/supp | oort nervous system health | | |
| Indication Requirem | nents | | | |
| Label statement: If s | ymptoms persist, talk to your health profe | ssional. | | |
| Product presentation | n must not imply or refer to mental illnesse | es, disorders or conditions. | | |
| Product presentation | must only refer to mild anxiety. | | | |
| Product presentation | n must not imply or refer to chronic fatigue | syndrome. | | |

Standard Indications

No Standard Indications included on Record

Specific Indications

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No Specific Indications included on Record

Warnings

'Contains gluten (or words to that effect)'

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 Tablet, film coated | |
| Route of Administration Oral | |
| Visual Identification | |
| Active Ingredients | |
| Avena sativa herb Extract dry concentrate | 100 mg |
| Equivalent: Avena sativa (Dry) | 1 g |
| Lavandula angustifolia herb Extract dry concentrate | 250 mg |
| Equivalent: Lavandula angustifolia (Dry) | 1 g |
| Panax quinquefolius root Extract dry concentrate | 300 mg |
| Equivalent: Panax quinquefolius (Dry) | 1.5 g |
| Rehmannia glutinosa root Extract dry concentrate | 416.667 mg |
| Equivalent: Rehmannia glutinosa (Dry) | 2.5 g |
| Other Ingredients (Excipients) | |
| croscarmellose sodium | |
| hyprolose | |
| macrogol 8000 | |
| magnesium stearate | |
| microcrystalline cellulose | |
| silicon dioxide | |
| stearic acid | |

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