



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|-----------------|
| Summary for ARTG Entry: | 312610 | Adrenergy Forte |
| ARTG entry for | Medicine Listed | |
| Sponsor | Bio-Practica Pty Ltd | |
| Postal Address | 651 Portrush Road, GLEN OSMOND, SA, 5064 Australia | |
| ARTG Start Date | 17/12/2018 | |
| 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 . Adrenergy Forte

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 17/12/2018 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in European herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Traditionally used in Central American medicine to maintain/support healthy digestion
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function
- Traditionally used in Eastern European herbal medicine to helps enhance/improve/promote/increase muscle performance/endurance/stamina
- Maintain/support muscle performance/endurance/stamina
- Traditionally used in Eastern European herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Central American medicine to adaptogen/Help body adapt to stress
- Traditionally used in Eastern European herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to aids/assists the body to cope with environmental stress
- Enhance/promote body adaptation to stress
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in European herbal medicine to decrease/reduce mental/cognitive fatigue
- Decrease/reduce mental/cognitive fatigue

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Traditionally used in Central American medicine to maintain/support mental concentration/focus/clarity
 Traditionally used in Eastern European herbal medicine to maintain/support mental endurance/stamina
 Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function
 Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function
 Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase memory/recall
 Traditionally used in Ayurvedic medicine to maintain/support brain function
 Traditionally used in Ayurvedic medicine to maintain/support nervous system health

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to serious immunological diseases.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must only refer to mild anxiety.

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 | Tablet, film coated |
| Route of Administration | Oral |

Visual Identification

Active Ingredients

| | |
|--|-----------------|
| Astragalus membranaceus | 150 mg |
| Equivalent: Astragalus membranaceus | 1.5 g |
| Bacopa monnieri | 60 mg |
| Equivalent: Bacopa monnieri | 1.2 g |
| Eleutherococcus senticosus | 200 mg |
| Equivalent: Eleutherococcus senticosus | 3 g |
| Panax quinquefolius | 50 mg |
| Equivalent: Panax quinquefolius | 500 mg |
| Rhodiola rosea | 137.5 mg |
| Equivalent: Rhodiola rosea | 1.1 g |
| Withania somnifera | 320 mg |
| Equivalent: Withania somnifera | 3.2 g |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
 Carnuba Wax
 colloidal anhydrous silica
 croscarmellose sodium
 crospovidone
 hypromellose

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macrogol 400
maltodextrin
microcrystalline cellulose
povidone
stearic acid

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