



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|---------------------|
| Summary for ARTG Entry: | 210977 | Mediherb Nervagesic |
| ARTG entry for | Medicine Listed | |
| Sponsor | Integria Healthcare Australia Pty Ltd | |
| Postal Address | PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia | |
| ARTG Start Date | 17/06/2013 | |
| 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.

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 . Mediherb Nervagesic

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 2/03/2021 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

- Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild migraine symptoms
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild nerve pain/neuralgia
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild sciatica
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual spasms/cramps
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea

Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild sciatica.
- Product presentation must only refer to mild migraine.
- Product presentation must only refer to mild nerve pain/neuralgia.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.



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For practitioner dispensing only.

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

| | |
|--|---------------|
| Corydalis turtschaninovii tuber Extract dry concentrate | 80 mg |
| Equivalent: Corydalis turtschaninovii (Dry) | 800 mg |
| Eschscholzia californica herb flowering Extract dry concentrate | 200 mg |
| Equivalent: Eschscholzia californica (Dry) | 800 mg |
| Piscidia piscipula stem bark Extract dry concentrate | 100 mg |
| Equivalent: Piscidia piscipula (Dry) | 400 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
sodium starch glycollate

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