

## **Australian Government**

# Department of Health and Aged Care

Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry: Mediherb Nervagesic 210977

ARTG entry for Medicine Listed

Sponsor Integria Healthcare Australia Pty Ltd

Postal Address PO Box 4854, EIGHT MILE PLAINS, QLD, 4113

17/06/2013 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

### 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** Effective Date 14/04/2025 Single Medicine Product

# **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**

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

Product presentation must only refer to mild migraine.

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

Product presentation must only refer to mild sciatica.

Product presentation must only refer to mild nerve pain/neuralgia.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

## Standard Indications

No Standard Indications included on Record

## **Specific Indications**

No Specific Indications included on Record

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

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Do not use if pregnant or likely to become pregnant (or words to that effect) For practitioner dispensing only.

## **Additional Product information**

Doole	Size/Pois	:	

Pack Size Poison Schedule

## Components

## 1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Ora

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 Ingradients (Evaluants)		

## 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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