

# **Australian Government**

## **Department of Health**

## Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 273907 MediHerb Nevaton Forte

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 7/04/2016
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 Nevaton Forte

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

# Permitted Indications

Support healthy stress response in the body

Traditionally used in Western herbal medicine to calms the mind

Traditionally used in Western herbal medicine to help maintain/support emotional wellbeing

Help maintain/support emotional wellbeing

Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy

Traditionally used in Western herbal medicine to soothe/calm nerves

Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety

Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of mild anxiety

Traditionally used in Western herbal medicine to nerve tonic

Traditionally used in Western herbal medicine to maintain/support nervous system health

Traditionally used in Western herbal medicine to calmative/nervous system relaxant

Traditionally used in Western herbal medicine to nervine/support nervous system

Support healthy emotional/mood balance

Traditionally used in Western herbal medicine to support healthy emotional/mood balance

Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep

## Indication Requirements

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

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

Product presentation must only refer to mild anxiety.

## **Standard Indications**

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Page 1 of 2



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### Warnings

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

For practitioner dispensing only.

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

### **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**

Crocus sativus stigma Extract dry concentrate	7.5 mg
Equivalent: Crocus sativus (Dry)	22.5 mg
Hypericum perforatum herb top flowering Extract dry concentrate standardised	125 mg
Equivalent: Hypericum perforatum (Dry)	750 mg
Schisandra chinensis fruit Extract dry concentrate	112.5 mg
Equivalent: Schisandra chinensis (Dry)	675 mg
Scutellaria lateriflora herb Extract liquid	1 mL
Equivalent: Scutellaria lateriflora (Dry)	500 mg

## Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

croscarmellose sodium

dextrin

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

sodium starch glycollate

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