



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
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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

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

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Warnings

For practitioner dispensing only.

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

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

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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