



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	377211	MediHerb St John's Wort
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	1/11/2021	
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 St John's Wort

Product Type	Single Medicine Product	Effective Date	1/11/2021
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Permitted Indications

- Help maintain/support emotional wellbeing
- Traditionally used in Western herbal medicine to 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 decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of mild anxiety
- Helps reduce occurrence of symptoms of mild anxiety
- Traditionally used in Western herbal medicine to maintain/support nervous system health
- 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 mild nerve pain/neuralgia
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild sciatica
- Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
- Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

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

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
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Hypericum perforatum herb top flowering Extract dry concentrate standardised	300 mg
Equivalent: Hypericum perforatum (Dry)	1.8 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

magnesium stearate

microcrystalline cellulose

sodium starch glycollate

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