Public Summary

Summary for ARTG Entry:	219716 REMOTIV
ARTG entry for	Medicine Listed
Sponsor	SFI Australasia
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia
ARTG Start Date	29/01/2014
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . REMOTIV

Product Type Single Medicine Product **Effective Date** 18/10/2019

Permitted Indications

Relieve irritability
Calms the mind
Help maintain/support emotional wellbeing
Soothe/calm nerves
Decrease/reduce/relieve symptoms of stress
Helps reduce occurrence of irritability
Decrease/reduce/relieve nervous tension/unrest
Decrease/reduce/relieve symptoms of mild anxiety
Helps reduce occurrence of symptoms of mild anxiety
Helps enhance/promote healthy nerve conduction/transmission/neurotransmission
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
Traditionally used in Western herbal medicine to nourish the nervous system
Support healthy emotional/mood balance

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

Warnings

Contains lactose (or words to that effect).

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

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

Hypericum perforatum herb top flowering Extract dry concentrate	**250 mg**
Equivalent: Hypericum perforatum (Dry)	1.375 g

Other Ingredients (Excipients)

hypromellose
iron oxide red
lactose monohydrate
macrogol 20000
macrogol 400
macrogol 6000
magnesium stearate
microcrystalline cellulose
propylene glycol
titanium dioxide

Public Summary