



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	219716	REMOTIV
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	SFI Australasia	
<b>Postal Address</b>	PO Box 1027, CROWS NEST, NSW, 1585 Australia	
<b>ARTG Start Date</b>	29/01/2014	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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
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**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.



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**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

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.

**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
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**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Hypericum perforatum herb top flowering Extract dry concentrate</b>	<b>250 mg</b>
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

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