



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	355014	STRESS PLEX
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	The Pharmaceutical Plant Company Pty Ltd	
<b>Postal Address</b>	3 Sigma Drive, Croydon South, VIC, 3136 Australia	
<b>ARTG Start Date</b>	16/02/2021	
<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.

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 . STRESS PLEX**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	16/02/2021
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**Permitted Indications**

- 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 symptoms of stress
- 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 calmative/nervous system relaxant

**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 ethanol or contains alcohol.
- 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**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

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Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

<b>Hypericum perforatum herb top flowering Extract liquid</b>	<b>125 microlitre/mL</b>
Equivalent: Hypericum perforatum (Dry)	125 mg/mL
<b>Melissa officinalis herb Extract liquid</b>	<b>150 microlitre/mL</b>
Equivalent: Melissa officinalis (Dry)	150 mg/mL
<b>Passiflora incarnata herb Extract liquid</b>	<b>125 microlitre/mL</b>
Equivalent: Passiflora incarnata (Dry)	125 mg/mL

Other Ingredients (Excipients)

ethanol

glycerol

Peppermint Oil

purified water

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