Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	229546	SLEEP PLEX
ARTG entry for	Medicine Listed	
Sponsor	The Pharmaceutical Plant Company Pty Ltd	
Postal Address	3 Sigma Drive, Croydon South, VIC, 3136 Australia	
ARTG Start Date	20/10/2014	
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 . SLEEP PLEX

Product Type Single Medicine Product **Effective Date** 2/08/2019

Permitted Indications

Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic

Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress

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 Ayurvedic medicine to soporific/induces sleep

Traditionally used in Western herbal medicine to soporific/induces sleep

Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

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

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

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 ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

Passiflora incarnata herb Extract liquid	**100 microlitre/mL**
Equivalent: Passiflora incarnata (Dry)	100 mg/mL
Scutellaria lateriflora leaf Extract liquid	**300 microlitre/mL**
Equivalent: Scutellaria lateriflora (Dry)	300 mg/mL
Withania somnifera root Extract liquid	**300 microlitre/mL**
Equivalent: Withania somnifera (Dry)	150 mg/mL

Other Ingredients (Excipients)

glycerol

Mentha X piperita

purified water