



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	342365	An Shen Ning Ye Fang a.k.a. Peaceful Sleep Formula
ARTG entry for	Medicine Listed	
Sponsor	Sun Herbal Pty Ltd	
Postal Address	Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	26/08/2020	
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.

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 . An Shen Ning Ye Fang a.k.a. Peaceful Sleep Formula

Product Type	Single Medicine Product	Effective Date	26/08/2020
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Permitted Indications

- Traditionally used in Chinese medicine to regulate Qi
- Traditionally used in Chinese medicine to nourish the heart
- Traditionally used in Chinese medicine to calm/soothe/nourish the liver
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit

Indication Requirements

- If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- For practitioner dispensing only.
- 'Contains gluten (or words to that effect)'

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Albizia julibrissin flower Extract dry concentrate	29.1 mg
Equivalent: Albizia julibrissin (Dry)	174.6 mg
Biota orientalis seed Extract dry concentrate	26.1 mg
Equivalent: Biota orientalis (Dry)	156.6 mg
Chrysanthemum sinense flower Extract dry concentrate	26.1 mg
Equivalent: Chrysanthemum sinense (Dry)	156.6 mg
Citrus reticulata fruit peel Extract dry concentrate	14.7 mg
Equivalent: Citrus reticulata (Dry)	88.2 mg
Citrus reticulata fruit pericarp Extract dry concentrate	14.7 mg
Equivalent: Citrus reticulata (Dry)	88.2 mg
Curcuma longa tuber Extract dry concentrate	26.1 mg
Equivalent: Curcuma longa (Dry)	156.6 mg
Glycyrrhiza uralensis root Extract dry concentrate	14.7 mg
Equivalent: Glycyrrhiza uralensis (Dry)	88.2 mg
Paeonia lactiflora root Extract dry concentrate	26.1 mg
Equivalent: Paeonia lactiflora (Dry)	156.6 mg
Rosa rugosa flower Extract dry concentrate	14.7 mg
Equivalent: Rosa rugosa (Dry)	88.2 mg
Schisandra chinensis fruit Extract dry concentrate	17.4 mg
Equivalent: Schisandra chinensis (Dry)	104.4 mg
Triticum aestivum seed Extract dry concentrate	35.1 mg
Equivalent: Triticum aestivum (Dry)	210.6 mg
Ziziphus jujuba fruit Extract dry concentrate	29.1 mg
Equivalent: Ziziphus jujuba (Dry)	174.6 mg
Ziziphus jujuba var. spinosa seed Extract dry concentrate	26.1 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	156.6 mg

Other Ingredients (Excipients)

hydrolysed gelatin

titanium dioxide

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