Public Summary

Summary for ARTG Entry:	218323 GUI PI WAN
ARTG entry for	Medicine Listed
Sponsor	Shen Neng Herbal Medicines Group Pty Ltd
Postal Address	1 Clarke Street, GUILDFORD, NSW, 2161 Australia
ARTG Start Date	10/12/2013
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'.

Sponsors must confirm the absence of aristolochic acids, in all medicines containing herbal material derived from any of the following plant genera - Akebia, Asarum, Bragantia, Clematis, Cocculus, Diploclisia, Menispermum, Saussurea, Sinomenium, Stephania, Vladimiria.
The confirmation must be undertaken by chemical analysis using Liquid Chromatography Mass Spectrometry (LC-MS). The methodology used should adhere to best practice according to contemporary scientific literature.
Confirmatory evidence is to be provided to the Director of Listing Compliance, Complementary and OTC Medicines Branch, prior to supply of each batch in Australia. The evidence submitted to the TGA is to include the certificate of analysis, all relevant details of the methodology, such as analytical method validation data, and the raw results.
All supporting evidence must be approved by the TGA prior to supply of the batch in Australia.

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 . GUI PI WAN

Product Type Single Medicine Product **Effective Date** 15/03/2021

Permitted Indications

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish spleen-qi

Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Traditionally used in Chinese medicine to helps enhance/promote general health and wellbeing

Traditionally used in Chinese medicine to soothe/calm nerves

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

Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep

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 not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to disease in any body organ.

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 chronic fatigue syndrome.

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Pill
Route of Administration	Oral
Visual Identification	

Active Ingredients

Angelica polymorpha root Powder	**51.72 mg**
Equivalent: Angelica polymorpha (Dry)	51.72 mg
Astragalus membranaceus root Extract soft concentrate	**6.1 mg**
Equivalent: Astragalus membranaceus (Dry)	25.86 mg
Atractylodes macrocephala rhizome Extract soft concentrate	**12.2 mg**
Equivalent: Atractylodes macrocephala (Dry)	51.72 mg
Codonopsis pilosula root Powder	**25.86 mg**
Equivalent: Codonopsis pilosula (Dry)	25.86 mg
dimocarpus longan seed aril Extract soft concentrate	**12.2 mg**
Equivalent: dimocarpus longan (Dry)	51.72 mg
Glycyrrhiza uralensis root and rhizome Powder	**12.93 mg**
Equivalent: Glycyrrhiza uralensis (Dry)	12.93 mg
Polygala tenuifolia root Extract soft concentrate	**12.2 mg**
Equivalent: Polygala tenuifolia (Dry)	51.72 mg
Saussurea costus root Powder	**12.93 mg**
Equivalent: Saussurea costus (Dry)	12.93 mg
Wolfiporia cocos hyphae Extract soft concentrate	**12.2 mg**
Equivalent: Wolfiporia cocos (Dry)	51.72 mg
Ziziphus jujuba fruit Extract soft concentrate	**3.05 mg**
Equivalent: Ziziphus jujuba (Dry)	12.93 mg
Ziziphus jujuba var. spinosa seed Extract soft concentrate	**6.1 mg**
Equivalent: Ziziphus jujuba var. spinosa (Dry)	25.86 mg

Other Ingredients (Excipients)

maize starch

purified talc

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