Public Summary

Summary for ARTG Entry:	100180	Geng Nian Fang a.k.a. Eucommia & Dang Gui Menopause 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	17/03/2004
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 . Geng Nian Fang a.k.a. Eucommia & Dang Gui Menopause Formula

Product Type	Single Medicine Product	**Effective Date**	11/05/2018

Permitted Indications

Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness

Traditionally used in Chinese medicine to dissipate retained-fluid/water

Traditionally used in Chinese medicine to regulate Qi

Traditionally used in Chinese medicine to soothe liver Qi

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

Traditionally used in Chinese medicine to enrich/nourish/tonify/fortify/strengthen kidneys

Traditionally used in Chinese medicine to calm/soothe/nourish the liver

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 liver disease, such as cirrhosis, hepatitis.

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

Product presentation must not imply or refer to kidney disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Alisma plantago aquatica rhizome Extract dry concentrate	**22.5 mg**
Equivalent: Alisma plantago aquatica (Dry)	135 mg
Angelica polymorpha root Extract dry concentrate	**22.5 mg**
Equivalent: Angelica polymorpha (Dry)	135 mg
Atractylodes macrocephala rhizome Extract dry concentrate	**22.5 mg**
Equivalent: Atractylodes macrocephala (Dry)	135 mg
Bupleurum falcatum root Extract dry concentrate	**15 mg**
Equivalent: Bupleurum falcatum (Dry)	90 mg
Codonopsis pilosula root Extract dry concentrate	**22.5 mg**
Equivalent: Codonopsis pilosula (Dry)	135 mg
Curcuma longa tuber Extract dry concentrate	**22.5 mg**
Equivalent: Curcuma longa (Dry)	135 mg
Cuscuta hygrophilae seed Extract dry concentrate	**22.5 mg**
Equivalent: Cuscuta hygrophilae (Dry)	135 mg
Dipsacus asper root Extract dry concentrate	**22.5 mg**
Equivalent: Dipsacus asper (Dry)	135 mg
Eucommia ulmoides stem bark Extract dry concentrate	**22.5 mg**
Equivalent: Eucommia ulmoides (Dry)	135 mg
Ligusticum striatum root Extract dry concentrate	**15 mg**
Equivalent: Ligusticum striatum (Dry)	90 mg
Loranthus parasiticus twig leafy Extract dry concentrate	**22.5 mg**
Equivalent: Loranthus parasiticus (Dry)	135 mg
Morus alba root bark Extract dry concentrate	**22.5 mg**
Equivalent: Morus alba (Dry)	135 mg
Paeonia lactiflora root Extract dry concentrate	**22.5 mg**
Equivalent: Paeonia lactiflora (Dry)	135 mg
Wolfiporia cocos fruiting body Extract dry concentrate	**22.5 mg**
Equivalent: Wolfiporia cocos (Dry)	135 mg

Other Ingredients (Excipients)

hydrolysed gelatin

titanium dioxide

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