



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	342376	Fang Tuo Sheng Fa Jiao Nang a.k.a. Hair Growth 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.

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 . Fang Tuo Sheng Fa Jiao Nang a.k.a. Hair Growth Formula

Product Type	Single Medicine Product	Effective Date	27/05/2022
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Permitted Indications

- Traditionally used in Chinese medicine to nourish/tonify/replenish strengthen liver-blood
- Traditionally used in Chinese medicine to nourish/tonify/warm/boost/invigorate/strengthen kidney-essence/kidney-jing
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify/invigorate spleen
- Traditionally used in Chinese medicine to enrich/nourish/tonify/fortify/strengthen kidneys
- Traditionally used in Chinese medicine to nourish/tonify/replenish kidney-yin
- Traditionally used in Chinese medicine to maintain/support hair growth in/of Kidney Jing Deficiency pattern
- Traditionally used in Chinese medicine to maintain/support hair growth in/of Kidney Yin Deficiency pattern
- Traditionally used in Chinese medicine to maintain/support hair growth in/of Liver Blood Deficiency pattern

Indication Requirements

- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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 kidney disease.
- Product presentation must not imply or refer to disease in any body organ.
- 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.

Additional Product information

Public Summary



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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Achyranthes bidentata root Extract dry concentrate	29.1 mg
Equivalent: Achyranthes bidentata (Dry)	174.6 mg
Anemone altaica rhizome Extract dry concentrate	15 mg
Equivalent: Anemone altaica (Dry)	90 mg
Angelica polymorpha root Extract dry concentrate	29.1 mg
Equivalent: Angelica polymorpha (Dry)	174.6 mg
Astragalus membranaceus root Extract dry concentrate	29.1 mg
Equivalent: Astragalus membranaceus (Dry)	174.6 mg
Cullen corylifolium seed Extract dry concentrate	22.2 mg
Equivalent: Cullen corylifolium (Dry)	133.2 mg
Cuscuta hygrophilae seed Extract dry concentrate	29.1 mg
Equivalent: Cuscuta hygrophilae (Dry)	174.6 mg
Lycium barbarum fruit Extract dry concentrate	29.1 mg
Equivalent: Lycium barbarum (Dry)	174.6 mg
Morus alba fruit Extract dry concentrate	29.1 mg
Equivalent: Morus alba (Dry)	174.6 mg
Panax ginseng root Extract dry concentrate	15 mg
Equivalent: Panax ginseng (Dry)	90 mg
Polygala sibirica root Extract dry concentrate	15 mg
Equivalent: Polygala sibirica (Dry)	90 mg
Rehmannia glutinosa root Extract dry concentrate	29.1 mg
Equivalent: Rehmannia glutinosa (Dry)	174.6 mg
Wolfiporia cocos hyphae Extract dry concentrate	29.1 mg
Equivalent: Wolfiporia cocos (Dry)	174.6 mg

Other Ingredients (Excipients)

Agar

carrageenan

hypromellose

sodium citrate

soluble maize starch

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