



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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| Summary for ARTG Entry: | 99761 | Du Huo Ji Sheng Tang (Jia Wei) a.k.a. Du Huo & Loranthus Arthritis 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 | 17/02/2004 | |
| 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'.

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.

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 . Du Huo Ji Sheng Tang (Jia Wei) a.k.a. Du Huo & Loranthus Arthritis Formula

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 6/04/2018 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

- Traditionally used in Chinese medicine to invigorate/activate Blood
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood
- Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness
- Traditionally used in Chinese medicine to enrich/nourish/tonify/fortify/strengthen kidneys
- Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear exogenous wind
- 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 serious cardiovascular conditions.
- Product presentation must not imply or refer to kidney disease.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Standard Indications



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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

| | |
|---|----------------|
| Achyranthes bidentata root Extract dry concentrate | 18 mg |
| Equivalent: Achyranthes bidentata (Dry) | 108 mg |
| Angelica polymorpha root Extract dry concentrate | 18 mg |
| Equivalent: Angelica polymorpha (Dry) | 108 mg |
| Angelica pubescens root Extract dry concentrate | 18 mg |
| Equivalent: Angelica pubescens (Dry) | 108 mg |
| Cinnamomum cassia stem bark Extract dry concentrate | 9 mg |
| Equivalent: Cinnamomum cassia (Dry) | 54 mg |
| Clematis chinensis root Extract dry concentrate | 18 mg |
| Equivalent: Clematis chinensis (Dry) | 108 mg |
| Codonopsis pilosula root Extract dry concentrate | 21 mg |
| Equivalent: Codonopsis pilosula (Dry) | 126 mg |
| Cyathula officinalis root Extract dry concentrate | 18 mg |
| Equivalent: Cyathula officinalis (Dry) | 108 mg |
| Cynanchum stauntonii root Extract dry concentrate | 19.5 mg |
| Equivalent: Cynanchum stauntonii (Dry) | 117 mg |
| Eucommia ulmoides stem bark Extract dry concentrate | 18 mg |
| Equivalent: Eucommia ulmoides (Dry) | 108 mg |
| Gentiana macrophylla root Extract dry concentrate | 18 mg |
| Equivalent: Gentiana macrophylla (Dry) | 108 mg |
| Glycyrrhiza uralensis root Extract dry concentrate | 9 mg |
| Equivalent: Glycyrrhiza uralensis (Dry) | 54 mg |
| Ledebouriella seseloides root Extract dry concentrate | 18 mg |
| Equivalent: Ledebouriella seseloides (Dry) | 108 mg |
| Ligusticum striatum root Extract dry concentrate | 18 mg |
| Equivalent: Ligusticum striatum (Dry) | 108 mg |
| Loranthus parasiticus stem Extract dry concentrate | 21 mg |
| Equivalent: Loranthus parasiticus (Dry) | 126 mg |
| Paeonia lactiflora root Extract dry concentrate | 19.5 mg |
| Equivalent: Paeonia lactiflora (Dry) | 117 mg |
| Rehmannia glutinosa root Extract dry concentrate | 18 mg |
| Equivalent: Rehmannia glutinosa (Dry) | 108 mg |
| Wolfiporia cocos fruiting body Extract dry concentrate | 21 mg |

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Equivalent: Wolfiporia cocos (Dry)

126 mg

Other Ingredients (Excipients)

hydrolysed gelatin

titanium dioxide

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