



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	148043	Hu Gan Jie Du Fang a.k.a. Liver Detox 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	4/12/2007	
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 . Hu Gan Jie Du Fang a.k.a. Liver Detox Formula

Product Type	Single Medicine Product	Effective Date	31/05/2018
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Permitted Indications

Traditionally used in Chinese medicine to invigorate/activate Blood

Traditionally used in Chinese medicine to eliminate/reduce/remove/resolve/dissipate blood-stasis

Traditionally used in Chinese medicine to clear/expel stagnant Heat

Traditionally used in Chinese medicine to regulate Qi

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

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 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.

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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

Atractylodes macrocephala rhizome Extract dry concentrate	22.68 mg
Equivalent: Atractylodes macrocephala (Dry)	136.08 mg
Bupleurum falcatum root Extract dry concentrate	22.68 mg
Equivalent: Bupleurum falcatum (Dry)	136.08 mg
Citrus aurantium fruit Extract dry concentrate	22.68 mg
Equivalent: Citrus aurantium (Dry)	136.08 mg
Curcuma longa tuber Extract dry concentrate	22.68 mg
Equivalent: Curcuma longa (Dry)	136.08 mg
Glycyrrhiza uralensis root Extract dry concentrate	10.08 mg
Equivalent: Glycyrrhiza uralensis (Dry)	60.48 mg
Lycium barbarum fruit Extract dry concentrate	22.68 mg
Equivalent: Lycium barbarum (Dry)	136.08 mg
Paeonia lactiflora root Extract dry concentrate	22.71 mg
Equivalent: Paeonia lactiflora (Dry)	136.26 mg
Paeonia suffruticosa root bark Extract dry concentrate	22.68 mg
Equivalent: Paeonia suffruticosa (Dry)	136.08 mg
Paeonia veitchii root Extract dry concentrate	22.71 mg
Equivalent: Paeonia veitchii (Dry)	136.26 mg
Pseudostellaria heterophylla root Extract dry concentrate	22.68 mg
Equivalent: Pseudostellaria heterophylla (Dry)	136.08 mg
Salvia miltiorrhiza root Extract dry concentrate	32.7 mg
Equivalent: Salvia miltiorrhiza (Dry)	196.2 mg
Scutellaria baicalensis root Extract dry concentrate	32.7 mg
Equivalent: Scutellaria baicalensis (Dry)	196.2 mg
Ziziphus jujuba fruit Extract dry concentrate	25.2 mg
Equivalent: Ziziphus jujuba (Dry)	151.2 mg

Other Ingredients (Excipients)

hydrolysed gelatin

soluble maize starch

titanium dioxide

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