



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 171412 ANTITOX 2 FORMULA a.k.a. Huang Lian Jie Du Tang

ARTG entry for Medicine Listed
Sponsor Sun Herbal Pty Ltd
Postal Address Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208
Australia
ARTG Start Date 14/05/2010
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 . ANTITOX 2 FORMULA a.k.a. Huang Lian Jie Du Tang

Product Type	Effective Date
Single Medicine Product	1/05/2018

Permitted Indications

Traditionally used in Chinese medicine to dispel/expel/disperse/clear fire

Traditionally used in Chinese medicine to remove Heat toxin

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 only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to drugs/alcohol.

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



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

coptis chinensis rhizome Extract dry concentrate	42.6 mg
Equivalent: coptis chinensis (Dry)	255.6 mg
Gardenia jasminoides fruit Extract dry concentrate	85.8 mg
Equivalent: Gardenia jasminoides (Dry)	514.8 mg
Phellodendron amurense stem bark Extract dry concentrate	85.8 mg
Equivalent: Phellodendron amurense (Dry)	514.8 mg
Scutellaria baicalensis root Extract dry concentrate	85.8 mg
Equivalent: Scutellaria baicalensis (Dry)	514.8 mg

Other Ingredients (Excipients)

Agar

carrageenan

hypromellose

sodium citrate dihydrate

soluble maize starch

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