# Public Summary

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| **Summary for ARTG Entry:** | 174251 URO-CLEAR FORMULA a.k.a. ba zhen tong lin fang |
| **ARTG entry for** | Medicine Listed |
| **Sponsor** | Sun Herbal Pty Ltd |
| **Postal Address** | Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208<br>Australia |
| **ARTG Start Date** | 26/07/2010 |
| **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'.

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 . URO-CLEAR FORMULA a.k.a. ba zhen tong lin fang

**Product Type** Single Medicine Product **Effective Date** 18/04/2018

#### Permitted Indications

Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness in/of Damp-Heat pattern

Traditionally used in Chinese medicine to dissipate retained-fluid/water in/of Damp-Heat pattern

Traditionally used in Chinese medicine to dispel/expel/disperse/clear internal/endogenous heat in/of Damp-Heat pattern

#### 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.

#### 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 |
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## Components

**1 . Formulation 1**

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| **Dosage Form** | Capsule, hard |
| **Route of Administration** | Oral |
| **Visual Identification** | |

### Active Ingredients

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| **Anemarrhena asphodeloides rhizome Extract dry concentrate** | **30 mg** |
| Equivalent: Anemarrhena asphodeloides (Dry) | 180 mg |
| **Clematis armandii stem Extract dry concentrate** | **20.1 mg** |
| Equivalent: Clematis armandii (Dry) | 120.6 mg |
| **Dianthus superbus herb Extract dry concentrate** | **30 mg** |
| Equivalent: Dianthus superbus (Dry) | 180 mg |
| **Gardenia jasminoides fruit Extract dry concentrate** | **30 mg** |
| Equivalent: Gardenia jasminoides (Dry) | 180 mg |
| **Glycyrrhiza uralensis root Extract dry concentrate** | **9.9 mg** |
| Equivalent: Glycyrrhiza uralensis (Dry) | 59.4 mg |
| **Juncus effusus stem pith Extract dry concentrate** | **9.9 mg** |
| Equivalent: Juncus effusus (Dry) | 59.4 mg |
| **Lygodium japonicum spore Extract dry concentrate** | **30 mg** |
| Equivalent: Lygodium japonicum (Dry) | 180 mg |
| **Phellodendron amurense stem bark Extract dry concentrate** | **30 mg** |
| Equivalent: Phellodendron amurense (Dry) | 180 mg |
| **Plantago asiatica seed Extract dry concentrate** | **30 mg** |
| Equivalent: Plantago asiatica (Dry) | 180 mg |
| **Polygonum aviculare herb Extract dry concentrate** | **30 mg** |
| Equivalent: Polygonum aviculare (Dry) | 180 mg |
| **Tetrapanax papyrifer stem Extract dry concentrate** | **20.1 mg** |
| Equivalent: Tetrapanax papyrifer (Dry) | 120.6 mg |

### Other Ingredients (Excipients)

**Agar**
**carrageenan**
**hypromellose**
**sodium citrate dihydrate**
**soluble maize starch**

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