



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|--|--|
| Summary for ARTG Entry: | 383884 | 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 Australia | |
| ARTG Start Date | 11/02/2022 | |
| 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 . URO-CLEAR FORMULA a.k.a. ba zhen tong lin fang

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 14/04/2022 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Traditionally used in Chinese medicine to clear/expel damp-heat from the bladder in/of Bladder Damp Heat pattern

Indication Requirements

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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

Container information

| Type | Material | Life Time | Temperature | Closure | Conditions |
|--------|--------------|--------------|--------------|--------------|--------------|
| Bottle | Not recorded | Not recorded | Not recorded | Not recorded | Not recorded |

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Formulation 1

| | |
|--------------------------------|---------------|
| Dosage Form | Capsule, hard |
| Route of Administration | Oral |

Visual Identification



Australian Government
Department of Health
Therapeutic Goods Administration

Active Ingredients

| | |
|--|----------------|
| Anemarrhena asphodeloides rhizome Extract dry concentrate | 30 mg |
| Equivalent: Anemarrhena asphodeloides (Dry) | 180 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 |
| Lysimachia christinae herb Extract dry concentrate | 20.1 mg |
| Equivalent: Lysimachia christinae (Dry) | 120.6 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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary