



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	63890	XIAO SHI BAO TONG CHONG JI - [Tummy Formula]
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Cathay Herbal Laboratories	
<b>Postal Address</b>	P O Box 6318, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	14/04/1998	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . XIAO SHI BAO TONG CHONG JI - [Tummy Formula]

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	9/04/2019
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#### Permitted Indications

Traditionally used in Chinese medicine to promote digestion and remove food stagnation in/of Food Accumulation in the Stomach pattern after eating in children

#### 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

Use in children under 12 years is not recommended.

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product (or words to that effect).

Prolonged use may cause serious bowel problems.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Keep out of reach of children (or words to that effect).

#### Additional Product information



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Granules

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Citrus reticulata fruit peel Extract dry concentrate</b>	<b>117.164 mg/g</b>
Equivalent: Citrus reticulata (Dry)	157 mg/g
<b>Crataegus cuneata fruit Extract dry concentrate</b>	<b>131.343 mg/g</b>
Equivalent: Crataegus cuneata (Dry)	176 mg/g
<b>Elettaria cardamomum fruit Extract dry concentrate</b>	<b>87.313 mg/g</b>
Equivalent: Elettaria cardamomum (Dry)	117 mg/g
<b>Forsythia suspensa fruit Extract dry concentrate</b>	<b>97.761 mg/g</b>
Equivalent: Forsythia suspensa (Dry)	131 mg/g
<b>Magnolia officinalis root bark Extract dry concentrate</b>	<b>73.134 mg/g</b>
Equivalent: Magnolia officinalis (Dry)	98 mg/g
<b>Oryza sativa fruit Extract dry concentrate</b>	<b>105.97 mg/g</b>
Equivalent: Oryza sativa (Dry)	142 mg/g
<b>Platycodon grandiflorus root Extract dry concentrate</b>	<b>73.134 mg/g</b>
Equivalent: Platycodon grandiflorus (Dry)	98 mg/g
<b>Raphanus sativus seed Extract dry concentrate</b>	<b>129.851 mg/g</b>
Equivalent: Raphanus sativus (Dry)	174 mg/g
<b>Rheum palmatum rhizome Extract dry concentrate</b>	<b>38.806 mg/g</b>
Equivalent: Rheum palmatum (Dry)	52 mg/g
<b>Wolfiporia cocos fruiting body Extract dry concentrate</b>	<b>146.269 mg/g</b>
Equivalent: Wolfiporia cocos (Dry)	196 mg/g

**Other Ingredients (Excipients)**

sucrose

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