Public Summary

Summary for ARTG Entry: 11660 BAO HE WAN [ Citrus & Crataegus Formula ]

ARTG entry for Medicine Listed
Sponsor Cathay Herbal Laboratories
Postal Address P O Box 6318, ALEXANDRIA, NSW, 2015
Australia
ARTG Start Date 19/08/1991
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. BAO HE WAN [ Citrus & Crataegus Formula ]

Product Type Single Medicine Product
Effective date 27/04/2005

Permitted Indications
No Permitted Indications included on Record

Indication Requirements
No Indication Requirements included on Record

Standard Indications
No Standard Indications included on Record

Specific Indications
This Traditional Chinese medicine has been used traditionally to help in the relief of symptoms of indigestion

Warnings
Keep out of reach of children (or words to that effect).
For practitioner dispensing only.
If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product Information

Pack Size/Poison information

Pack Size

Components
1. Medicine Component

Poison Schedule
<table>
<thead>
<tr>
<th>Active Ingredients</th>
<th>Dosage</th>
<th>Equivalent (Dry)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citrus reticulata</td>
<td>4.429 mg</td>
<td>10.629 mg</td>
</tr>
<tr>
<td>Crataegus pinnatifida</td>
<td>26.554 mg</td>
<td>63.729 mg</td>
</tr>
<tr>
<td>Forsythia suspensa</td>
<td>4.429 mg</td>
<td>10.629 mg</td>
</tr>
<tr>
<td>Hordeum vulgare</td>
<td>4.429 mg</td>
<td>10.629 mg</td>
</tr>
<tr>
<td>Pinellia ternata</td>
<td>8.854 mg</td>
<td>21.249 mg</td>
</tr>
<tr>
<td>Raphanus sativus</td>
<td>4.429 mg</td>
<td>10.629 mg</td>
</tr>
<tr>
<td>Wolfiporia cocos</td>
<td>8.854 mg</td>
<td>21.249 mg</td>
</tr>
</tbody>
</table>