



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

|                                |  |                |
|--------------------------------|--|----------------|
| <b>Summary for ARTG Entry:</b> | 239115   | Vitex Capsules |
| <b>ARTG entry for</b>          | Medicine Listed  |                |
| <b>Sponsor</b>                 | FIT-BioCeuticals Limited   |                |
| <b>Postal Address</b>          | Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102<br>Australia |                |
| <b>ARTG Start Date</b>         | 27/05/2015   |                |
| <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.

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 . Vitex Capsules

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 17/06/2021 |
|---------------------|-------------------------|-----------------------|------------|

#### Permitted Indications

Traditionally used in Western herbal medicine to maintain/support female reproductive system health

Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods

Traditionally used in Western herbal medicine to maintain/support/regulate healthy menstrual cycle

Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea

Traditionally used in Western herbal medicine to decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension

#### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).

#### Additional Product information

#### Pack Size/Poison information

|                  |                        |
|------------------|------------------------|
| <b>Pack Size</b> | <b>Poison Schedule</b> |
|------------------|------------------------|

#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

#### Visual Identification

#### Active Ingredients



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|  |               |
|--|---------------|
| <b>Vitex agnus-castus fruit Extract dry concentrate standardised</b> | <b>100 mg</b> |
| Equivalent: Vitex agnus-castus (Dry)                                 | 1000 mg       |

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
hypromellose  
magnesium stearate  
maltodextrin  
purified water

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