



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

## Public Summary

|                                |   |                               |
|--------------------------------|---|-------------------------------|
| <b>Summary for ARTG Entry:</b> | 315762  | Hey Sister! Period 42 Tablets |
| <b>ARTG entry for</b>          | Medicine Listed                                     |                               |
| <b>Sponsor</b>                 | Bioactive Laboratories Pty Ltd                      |                               |
| <b>Postal Address</b>          | 56 Alderbury Street, Floreat, WA, 6014<br>Australia |                               |
| <b>ARTG Start Date</b>         | 26/03/2019  |                               |
| <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 . Hey Sister! Period 42 Tablets

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 24/05/2024 |
|---------------------|-------------------------|-----------------------|------------|

### Permitted Indications

Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness  
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention  
Traditionally used in Western herbal medicine to helps reduce occurrence of abdominal bloating  
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm  
Traditionally used in Western herbal medicine to helps reduce occurrence of abdominal spasm  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of heartburn  
Traditionally used in Western herbal medicine to decrease/reduce/relieve gastrointestinal pain  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety  
Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual spasms/cramps  
Traditionally used in Western herbal medicine to decrease/reduce heavy menstruation/periods  
Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea  
Traditionally used in Western herbal medicine to decrease/reduce feelings of aggression/irritability associated with premenstrual tension  
Traditionally used in Western herbal medicine to decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension  
Traditionally used in Western herbal medicine to decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension  
Traditionally used in Western herbal medicine to help decrease/reduce/relieve confusion associated with premenstrual tension/syndrome  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of premenstrual tension  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menstruation

### Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
Product presentation must not imply or refer to gastro oesophageal reflux disease.  
Product presentation must not imply or refer to chronic fatigue syndrome.  
Label statement: If symptoms persist, talk to your health professional.  
Product presentation must only refer to mild anxiety.

### Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

Not for prolonged use. If symptoms persist, seek advice from a health care practitioner. Not recommended for use by pregnant or lactating women (or words to that effect). May harm the liver.

If symptoms persist, seek the advice of a healthcare professional.

Do not use for more than 7 days.

Do not use if pregnant or likely to become pregnant (or words to that effect)

Use in children under 12 years is not recommended.

Not for prolonged use. May harm liver.

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             | Tablet, film coated |
| Route of Administration | Oral                |
| Visual Identification   |                     |

Active Ingredients

|                                   |        |
|-----------------------------------|--------|
| Khaya senegalensis stem bark Dry  | 500 mg |
| Equivalent: Khaya senegalensis () | 500 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

croscarmellose sodium

crospovidone

glyceryl monostearate

hypromellose

macrogol 400

macrogol 6000

magnesium stearate

microcrystalline cellulose

povidone

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