Public Summary

Summary for ARTG Entry:	76828 PREMULAR
ARTG entry for	Medicine Listed
Sponsor	SFI Australasia
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia
ARTG Start Date	15/11/2000
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 . PREMULAR

Product Type Single Medicine Product **Effective Date** 18/10/2019

Permitted Indications

Temporarily relieve mild fluid retention in premenstrual woman

Aid/assist/helps in the management of food cravings in premenstrual woman

Decrease/reduce/relieve abdominal bloating/distention in premenstrual woman

Helps reduce occurrence of abdominal bloating in premenstrual woman

Relieve irritability in premenstrual woman

Helps reduce occurrence of irritability in premenstrual woman

Decrease/reduce/relieve headache symptoms in premenstrual woman

Helps reduce occurrence of symptoms of headaches in premenstrual woman

Maintain/support neuroendocrine function in premenstrual woman

Decrease/reduce/relieve disturbed/restless sleep in premenstrual woman

Maintain/support female healthy hormonal balance during the reproductive cycle

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

Maintain/support female reproductive system health in premenstrual woman

Improve menstrual flow

Decrease/reduce/relieve menstrual cycle irregularity/irregular periods

Maintain/support/regulate healthy menstrual cycle

Decrease/reduce/relieve menstrual spasms/cramps

Decrease/reduce heavy menstruation/periods

Decrease/reduce/relieve menstruation pain/dysmenorrhoea

Decrease/reduce feelings of aggression/irritability associated with premenstrual tension

Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension

Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension

Decrease/reduce/relieve symptoms of premenstrual tension

Decrease/reduce/relieve symptoms of premenstrual tension

Linked indication - Temporarily relieve mild fluid retention
Linked indication - Aid/assist/helps in the management of food cravings
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Linked indication - Helps reduce occurrence of abdominal bloating
Linked indication - Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
Linked indication - Decrease/reduce/relieve disturbed/restless sleep
Linked indication - Decrease/reduce/relieve menstrual spasms/cramps
Linked indication - Decrease/reduce feelings of aggression/irritability associated with premenstrual tension
Linked indication - Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
Linked indication - Helps reduce occurrence of symptoms of headaches

Helps reduce occurrence of premenstrual tension symptoms

Maintain/support healthy reproductive hormones in premenstrual woman

Indication Requirements

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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: If fluid retention persists, seek medical advice (or words to that effect).

Product presentation must not imply or refer to cardiovascular or renal conditions.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must only refer to mild fluid retention.

Product presentation must not imply or refer to hormone imbalances.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains lactose (or words to that effect).

If fluid retention persists, seek medical advice (or words to that effect).

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

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	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

Vitex agnus-castus fruit Extract dry concentrate	**20 mg**
Equivalent: Vitex agnus-castus (Dry)	180 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose
lactose monohydrate
macrogol 20000
macrogol 400
magnesium stearate
microcrystalline cellulose
propylene glycol
titanium dioxide

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