Public Summary

Summary for ARTG Entry:	339650 BLACKMORES VITAMIN B6
ARTG entry for	Medicine Listed
Sponsor	Blackmores Ltd
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia
ARTG Start Date	16/07/2020
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.

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 . BLACKMORES VITAMIN B6

Product Type Single Medicine Product **Effective Date** 16/07/2020

Permitted Indications

Maintain/support energy levels

Temporarily relieve mild fluid retention

Maintain/support general health and wellbeing

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Aid/assist/helps protein synthesis in the body

Maintain/support nervous system function

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

Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Product presentation must only refer to mild fluid retention.

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

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

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

WARNING - this medication may be dangerous when used in large amounts or for a long time; or WARNING - this product contains [insert pyridoxine hydrochloride or pyridoxal 5-phosphate as applicable], which may be dangerous when used in large amounts or for a long time.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Tablet, modified release
Route of Administration	Oral
Visual Identification	

Active Ingredients

pyridoxine hydrochloride	**121.55 mg**
Equivalent: pyridoxine	100 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
Carnauba Wax
Guar Gum
hydrogenated vegetable oil
hypromellose
iron oxide yellow
macrogol 400
macrogol 8000
magnesium phosphate pentahydrate
magnesium stearate
purified talc
titanium dioxide