**Public Summary**

**Summary for ARTG Entry:** 99231

**Nature's Own Vitamin B6 200mg**

**ARTG entry for Medicine Listed**

**Sponsor**
Sanofi-Aventis Healthcare Pty Ltd T/A Sanofi Consumer Healthcare

**Postal Address**
PO Box 403, VIRGINIA, QLD, 4014 Australia

**ARTG Start Date**
19/01/2004

**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. Nature’s Own Vitamin B6 200mg**

**Product Type**
Single Medicine Product

**Effective date**
21/10/2009

**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

Relief of pre-menstrual symptoms/syndrome. [Warning S required]

For the symptomatic relief of pre-menstrual tension/syndrome. [Warning S required]

For vitamin (may state the vitamin) supplementation.

**Specific Indications**

*LABEL COPY:* Relief of PMS symptoms. Helping to relieve PMS symptoms including irritability and mood changes. Vitamin B6 is necessary for the formation of haemoglobin and red blood cells. It is involved in the manufacture of several neurotransmitters and may be beneficial in relieving the symptoms of PMS including mood changes.

*ADDITIONAL CLAIMS:* The elderly may have an additional requirement for Vitamin B6. Plays a role in maintaining a healthy immune system. Required for the healthy development and functioning of the nervous system. Aids in the formation of several neurotransmitters and is needed to make serotonin, melatonin, dopamine and therefore an essential nutrient in the regulation of mental processes and possibly mood. Facilitates the metabolism of amino acids, fats and carbohydrates. May help to maintain healthy cardiovascular system. May help provide relief from the symptoms of morning sickness, including nausea and vomiting. Helps relieve the intensity of nausea in pregnancy. May help relieve PMS symptoms including mood swings, irritability, tiredness and fatigue.

*LABEL COPY:* Vitamin B6 is used for:
- helping to relieve PMS symptoms including mild fluid retention, irritability and abdominal bloating.
- helping to relieve the intensity of nausea in pregnancy.

How it works:
Vitamin B6 is needed for the production of prostaglandins and is necessary for the formation of haemoglobin and red blood cells. It is involved in the...
manufacture of several neurotransmitters, and is beneficial in relieving the symptoms of PMS including mood changes.

**Warnings**

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.

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

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

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

**Additional Product Information**

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<thead>
<tr>
<th>Pack Size/Poison information</th>
<th>Poisen Schedule</th>
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<tbody>
<tr>
<td>Components</td>
<td></td>
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<tr>
<td>1. Formulation 1</td>
<td></td>
</tr>
<tr>
<td>Dosage Form</td>
<td>Tablet, uncoated</td>
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<tr>
<td>Route of Administration</td>
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<tr>
<td>Active Ingredients</td>
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<tr>
<td>pyridoxine hydrochloride</td>
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