



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

**Public Summary**

|                                |   |         |
|--------------------------------|---|---------|
| <b>Summary for ARTG Entry:</b> | 228775  | Allimax |
| <b>ARTG entry for</b>          | Medicine Listed                                 |         |
| <b>Sponsor</b>                 | Biomedica Nutraceuticals Pty Ltd                |         |
| <b>Postal Address</b>          | PO Box 7052, ALEXANDRIA, NSW, 2015<br>Australia |         |
| <b>ARTG Start Date</b>         | 1/10/2014                                       |         |
| <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.

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 . Allimax**

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 26/07/2019 |
|---------------------|-------------------------|-----------------------|------------|

**Permitted Indications**

- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration
- Helps in the maintenance of healthy blood lipids/blood fats
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Traditionally used in Western herbal medicine to vermifuge/helps remove intestinal threadworms/pinworms
- Traditionally used in Western herbal medicine to decongestant/relieve nasal congestion
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion
- Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase cough productivity

**Indication Requirements**

- Label statement: If symptoms persist, talk to your health professional.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Respiratory tract infections must be qualified by 'mild'.
- Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.
- Product presentation must not imply or refer to serious cardiovascular conditions.

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Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

**Allium sativum bulb Extract dry** **180 mg**

Equivalent: Allium sativum (Fresh) 3.6 mg

**Allium sativum bulb Extract dry concentrate standardised** **75 mg**

Equivalent: Allium sativum (Fresh) 900 mg

**Other Ingredients (Excipients)**

Acacia

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

dl-alpha-tocopherol

Garlic Bulb Powder

hypromellose

maltodextrin

microcrystalline cellulose

purified water

silicon dioxide

sorbitol

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