



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

**Public Summary**

**Summary for ARTG Entry:** 289775 EAGLE MAG-ORO TABLETS

<b>ARTG entry for</b>	Medicine Listed
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia
<b>ARTG Start Date</b>	6/06/2017
<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.

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 . EAGLE MAG-ORO TABLETS**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/05/2020
---------------------	-------------------------	-----------------------	-----------

**Permitted Indications**

- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Maintain/support healthy cardiovascular system function
- Maintain/support healthy muscle contraction function
- Maintain/support muscle health
- Maintain/support muscle health in females
- Maintain/support muscle health In older females
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support muscle relaxation
- Maintain/support muscle tone
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters

**Indication Requirements**

- If product is indicated for supplementation, Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
- 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 not imply or refer to mental illnesses, disorders or conditions.

Public Summary



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

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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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

**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).

For practitioner dispensing only.

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
-----------	-----------------

**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>magnesium amino acid chelate</b>	<b>176.5 mg</b>
Equivalent: magnesium	35.3 mg
<b>magnesium aspartate dihydrate</b>	<b>275 mg</b>
Equivalent: magnesium	20.6 mg
<b>magnesium orotate dihydrate</b>	<b>350 mg</b>
Equivalent: magnesium	23 mg
<b>potassium aspartate</b>	<b>121.1 mg</b>
Equivalent: potassium	26.3 mg
<b>pyridoxine hydrochloride</b>	<b>5 mg</b>
Equivalent: pyridoxine	4.11 mg

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- hypromellose
- hypromellose
- magnesium stearate
- microcrystalline cellulose

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.