



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

## Public Summary

<b>Summary for ARTG Entry:</b>	338577	Floradix Liquid Magnesium
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Endeavour CH Pty Ltd	
<b>Postal Address</b>	Endeavour Consumer Health, Level 7 737 Bourke St, Docklands, VIC, 3008 Australia	
<b>ARTG Start Date</b>	29/06/2020	
<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.

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 . Floradix Liquid Magnesium

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/08/2021
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### Permitted Indications

- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support vitality
- Maintain/support general health and wellbeing
- Maintain/support bone health
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support healthy muscle contraction function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
- Maintain/support nervous system health
- Maintain/support nervous system function

### Indication Requirements

- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- 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 chronic fatigue syndrome.



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**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Not suitable for infants under the age of twelve months (or words to that effect).

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Use in children under 12 years is not recommended.

Do not use while breastfeeding.

Do not use if pregnant or likely to become pregnant (or words to that effect)

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Citrus aurantium fruit peel Infusion</b>	<b>401 mg/mL</b>
Equivalent: Citrus aurantium (Dry)	2.5 mg/mL
<b>Daucus carota root Infusion</b>	<b>401 mg/mL</b>
Equivalent: Daucus carota (Dry)	2.5 mg/mL
<b>dibasic magnesium citrate tetrahydrate</b>	<b>71 mg/mL</b>
Equivalent: magnesium	5.7 mg/mL
<b>Foeniculum vulgare seed Infusion</b>	<b>401 mg/mL</b>
Equivalent: Foeniculum vulgare (Dry)	2.5 mg/mL
<b>magnesium gluconate</b>	<b>136 mg/mL</b>
Equivalent: magnesium	6.8 mg/mL
<b>Matricaria chamomilla flower Infusion</b>	<b>401 mg/mL</b>
Equivalent: Matricaria chamomilla (Dry)	2.5 mg/mL
<b>Spinacia oleracea leaf Infusion</b>	<b>401 mg/mL</b>
Equivalent: Spinacia oleracea (Dry)	2 mg/mL

**Other Ingredients (Excipients)**

**Apricot**

**Flavour**

**Honey**

**Mango**

**Pear**

**Pineapple**

**purified water**

Public Summary

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