



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	338578	Floradix Liquid Calcium and Magnesium
ARTG entry for	Medicine Listed	
Sponsor	Endeavour CH Pty Ltd	
Postal Address	Endeavour Consumer Health, Level 7 737 Bourke St, Docklands, VIC, 3008 Australia	
ARTG Start Date	29/06/2020	
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.

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 Calcium and Magnesium

Product Type	Single Medicine Product	Effective Date	27/08/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support bone health
- Maintain/support cardiovascular system health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle 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
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support nerve conduction
- Maintain/support nervous system function
- Maintain/support female reproductive system health
- Maintain/support reproductive system health
- Maintain/support healthy reproductive hormones
- Maintain/support skin health
- Maintain/support wound healing

Indication Requirements

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

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).

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).



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

Product presentation must not imply or refer to serious immunological diseases.

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 hormone imbalances.

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

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 infertility.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not use if pregnant or likely to become pregnant (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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral

Visual Identification

Active Ingredients

calcium gluconate monohydrate	34.95 mg/mL
Equivalent: calcium	3.25 mg/mL
calcium lactate pentahydrate	13.98 mg/mL
Equivalent: calcium	1.91 mg/mL
colecalfiferol	.17 microgram/mL
dibasic magnesium citrate tetrahydrate	18.8 mg/mL
Equivalent: magnesium	1.6 mg/mL
magnesium gluconate	84.75 mg/mL
Equivalent: magnesium	4.6 mg/mL
zinc citrate trihydrate	.38 mg/mL
Equivalent: zinc	.117 mg/mL

Other Ingredients (Excipients)

- Ceratonia siliqua**
- Citrus sinensis**
- Foeniculum vulgare**
- fructose**
- Hibiscus sabdariffa**
- Mangifera indica**
- Matricaria chamomilla**
- purified water**
- Spinach**

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