



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	78903	Floradix Magnesium Mineral Drink
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	31/05/2001	
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 Magnesium Mineral Drink

Product Type	Single Medicine Product	Effective Date	18/12/2020
---------------------	-------------------------	-----------------------	------------

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 when dietary intake is inadequate
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support nervous system health
- Maintain/support nervous system function

Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- 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.
- 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 serious musculoskeletal or neurological 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 serious cardiovascular conditions.

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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

Do not use while breastfeeding.

Use in children under 12 years is not recommended.

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].

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

Chamaemelum nobile flower Decoction	82.5 mg/mL
Equivalent: Chamaemelum nobile (Dry)	2.5 mg/mL
Citrus aurantium fruit peel Decoction	82.5 mg/mL
Equivalent: Citrus aurantium (Dry)	2.5 mg/mL
Daucus carota fruit Decoction	82.5 mg/mL
Equivalent: Daucus carota (Dry)	2.5 mg/mL
Foeniculum vulgare seed Decoction	82.5 mg/mL
Equivalent: Foeniculum vulgare (Dry)	2.5 mg/mL
magnesium citrate	71 mg/mL
Equivalent: magnesium	5.7 mg/mL
magnesium gluconate	136 mg/mL
Equivalent: magnesium	6.8 mg/mL
Spinacia oleracea leaf Decoction	66 mg/mL
Equivalent: Spinacia oleracea (Dry)	2 mg/mL

Other Ingredients (Excipients)

Apricot

Honey

Mango

Pear

Pineapple

Prunus persica

purified water

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>.