



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	361470	Eagle Clinical CalMag Complete
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	12/04/2021	
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 . Eagle Clinical CalMag Complete

Product Type	Single Medicine Product	Effective Date	12/04/2021
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Permitted Indications

- Helps convert (state food) into energy
- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Maintain/support healthy cardiovascular system function
- Maintain/support healthy muscle contraction function
- Maintain/support muscle health
- 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

Indication Requirements

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 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 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.

Public Summary



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

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

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 mental illnesses, disorders or conditions.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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 symptoms persist, seek the advice of a healthcare professional.

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

calcium citrate tetrahydrate	685 mg
Equivalent: calcium	144.6 mg
calcium hydrogen phosphate dihydrate	452 mg
Equivalent: calcium	105 mg
colecalfiferol	.005 mg
copper gluconate	.715 mg
Equivalent: copper	.1 mg
heavy magnesium oxide	132.7 mg
Equivalent: magnesium	80 mg
magnesium amino acid chelate	200 mg
Equivalent: magnesium	40 mg
manganese amino acid chelate	25 mg
Equivalent: manganese	5 mg
silicon dioxide	50 mg
Equivalent: silicon	23.35 mg
zinc amino acid chelate	50 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

crospovidone

dl-alpha-tocopherol

hydrogenated soya oil

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hydrolysed gelatin
lecithin
macrogol 3000
magnesium stearate
maize starch
microcrystalline cellulose
polyvinyl alcohol
povidone
purified talc
silicon dioxide
sucrose
titanium dioxide

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Public Summary