



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

**Public Summary**

|                                |                                                 |                                 |
|--------------------------------|-------------------------------------------------|---------------------------------|
| <b>Summary for ARTG Entry:</b> | 273037                                          | METAGENICS CALCITITE OSTEO TABS |
| <b>ARTG entry for</b>          | Medicine Listed                                 |                                 |
| <b>Sponsor</b>                 | Metagenics (Aust) Pty Ltd                       |                                 |
| <b>Postal Address</b>          | PO Box 675, VIRGINIA BC, QLD, 4014<br>Australia |                                 |
| <b>ARTG Start Date</b>         | 17/03/2016                                      |                                 |
| <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 . METAGENICS CALCITITE OSTEO TABS**

| Product Type | Single Medicine Product | Effective Date | 10/12/2020 |
|--------------|-------------------------|----------------|------------|
|--------------|-------------------------|----------------|------------|

**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support connective tissue health
- Maintain/support body tissue repair/regeneration
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support bone mass/density/integrity in post-menopausal women
- Maintain/support bone mass/density/integrity
- Maintain/support bone strength
- Maintain/support bone strength In older males
- Maintain/support bone strength in children
- Maintain/support bone strength In older females
- Help maintain/support bone mineralisation
- Help maintain/support bone mineralisation in post-menopausal women
- A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate in post-menopausal women
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life in post-menopausal women
- Helps enhance/improve/promote/increase muscle strength to improve balance/stability in elderly individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in post-menopausal women

**Indication Requirements**

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.

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

Public Summary



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inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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.

Indication can only be used for medicines that contain calcium as an active ingredient and the recommended daily dose of the medicine must provide at least 290 milligrams of elemental calcium.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Not to be taken by children under 12 years old (or words to that effect).

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

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.

**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**

|                                                                           |                  |
|---------------------------------------------------------------------------|------------------|
| <b>ascorbic acid</b>                                                      | <b>125 mg</b>    |
| <b>borax</b>                                                              | <b>13.23 mg</b>  |
| Equivalent: boron                                                         | 1.5 mg           |
| <b>colecalfiferol</b>                                                     | <b>.0062 mg</b>  |
| <b>Glycine max pressed seed cake Extract dry concentrate standardised</b> | <b>56.25 mg</b>  |
| Equivalent: Glycine max (Dry)                                             | 9 g              |
| <b>hydroxyapatite</b>                                                     | <b>980.39 mg</b> |
| Equivalent: calcium                                                       | 250 mg           |
| Equivalent: phosphorus                                                    | 107.84 mg        |
| <b>manganese amino acid chelate</b>                                       | <b>7.81 mg</b>   |
| Equivalent: manganese                                                     | 1.25 mg          |
| <b>phytomenadione</b>                                                     | <b>.05 mg</b>    |
| <b>zinc amino acid chelate</b>                                            | <b>12.5 mg</b>   |
| Equivalent: zinc                                                          | 2.5 mg           |

**Other Ingredients (Excipients)**

Acacia  
 citric acid  
 colloidal anhydrous silica  
 croscarmellose sodium  
 dl-alpha-tocopherol  
 hyplose  
 macrogol 8000  
 magnesium stearate  
 maize starch  
 maltodextrin  
 medium chain triglycerides  
 microcrystalline cellulose

Public Summary



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

povidone  
silicon dioxide  
stearic acid  
sucrose

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