Public Summary

Summary for ARTG Entry:	344313	METAGENICS CALCITITE OSTEO POWDER
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	24/09/2020	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 POWDER

Product Type	Single Medicine Product	**Effective Date**	24/09/2020

Permitted Indications

Maintain/support collagen formation

Maintain/support connective tissue health

Maintain/support body tissue repair/regeneration

Maintain/support bone health

Maintain/support bone health in elderly individuals

Aids/assists healthy bone development/growth/building

Maintain/support bone mass/density/integrity in elderly individuals

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 children

Maintain/support bone strength in elderly individuals

Maintain/support bone strength in post-menopausal women

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

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.

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.

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.

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	

Active Ingredients

ascorbic acid	**64.1 mg/g**
borax	**6.78 mg/g**
Equivalent: boron	768.85 microgram/g
colecalciferol	**.0032 mg/g**
Glycine max pressed seed cake Extract dry concentrate standardised	**28.85 mg/g**
Equivalent: Glycine max (Dry)	4.615 g/g
hydroxyapatite	**502.77 mg/g**
Equivalent: calcium	128.21 mg/g
Equivalent: phosphorus	55.3 mg/g
manganese amino acid chelate	**4.01 mg/g**
Equivalent: manganese	641.03 microgram/g
phytomenadione	**25.641 microgram/g**
zinc amino acid chelate	**6.41 mg/g**
Equivalent: zinc	1.28 mg/g

Other Ingredients (Excipients)

Acacia
citric acid
dl-alpha-tocopherol
Flavour
maize starch
maltodextrin
medium chain triglycerides

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silicon dioxide

Steviol glycosides

sucrose

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