



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|-----------|
| Summary for ARTG Entry: | 380595 | Calcium + |
| ARTG entry for | Medicine Listed | |
| Sponsor | JSHealth Vitamins Pty Ltd | |
| Postal Address | 14/409 New South Head Road, Double Bay, Sydney, NSW, 2028 Australia | |
| ARTG Start Date | 10/12/2021 | |
| 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 . Calcium +

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 14/12/2022 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Maintain/support general health and wellbeing

Maintain/support healthy teeth

Maintain/support bone health

Maintain/support bone mass/density/integrity

Maintain/support bone strength

Help maintain/support bone mineralisation

A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate

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 heart health

Maintain/support healthy digestive system function

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support healthy muscle contraction function

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in elderly individuals

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate

Maintain/support nerve conduction

Maintain/support neuromuscular function

Maintain/support nervous system function

Indication Requirements



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

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).

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

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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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

No Warnings included on Record

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 | 1.0804 g |
| Equivalent: calcium | 250 mg |
| colecalfiferol | .0062 mg |

Other Ingredients (Excipients)

Acacia

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

crospovidone

d-alpha-tocopherol

fractionated coconut oil

glycerol

hypromellose

liquid glucose

magnesium stearate

microcrystalline cellulose

povidone

pregelatinised rice starch

silicon dioxide

sodium ascorbate

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