Public Summary

Summary for ARTG Entry:	94753 Super Calcium Plus with Boron
ARTG entry for	Medicine Listed
Sponsor	Herbs of Gold Pty Ltd
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia
ARTG Start Date	10/06/2003
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 . Super Calcium Plus with Boron

Product Type	Single Medicine Product	**Effective Date**	28/05/2020

Permitted Indications

Maintain/support general health and wellbeing
Maintain/support healthy teeth
Maintain/support teeth mineralisation
Maintain/support bone health in post-menopausal women
Maintain/support bone health
Maintain/support bone mass/density/integrity
Maintain/support bone mass/density/integrity in post-menopausal women
Maintain/support bone strength in post-menopausal women
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 cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support healthy muscle contraction function
Maintain/support muscle health
Maintain/support muscle function
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support nervous system health
Maintain/support nervous system function

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).

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.

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

Product presentation must not imply or refer to serious cardiovascular 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

Not to be taken by children under 2 years old (or words to that effect).

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

borax	**8.82 mg**
Equivalent: boron	1 mg
calcium citrate tetrahydrate	**1.126 g**
Equivalent: calcium	237.3 mg
colecalciferol	**.0025 mg**
Equisetum arvense herb Extract dry concentrate	**10 mg**
Equivalent: Equisetum arvense (Dry)	50 mg
hydroxyapatite	**162.5 mg**
Equivalent: calcium	39 mg
magnesium oxide	**207.3 mg**
Equivalent: magnesium	125 mg
manganese amino acid chelate	**15 mg**
Equivalent: manganese	1.5 mg
phytomenadione	**2.5 microgram**
zinc gluconate	**2.3 mg**
Equivalent: zinc	300 microgram

Other Ingredients (Excipients)

Acacia
Carnauba Wax
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
hydrogenated soya oil

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hydrogenated vegetable oil
hydrolysed gelatin
hypromellose
macrogol 400
magnesium stearate
maize starch
povidone
silicon dioxide
stearic acid
sucrose
titanium dioxide

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