Public Summary

Summary for ARTG Entry:	324012 Children's Calci Care
ARTG entry for	Medicine Listed
Sponsor	Herbs of Gold Pty Ltd
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia
ARTG Start Date	25/09/2019
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Children's Calci Care

Product Type Single Medicine Product **Effective Date** 25/09/2019

Permitted Indications

Maintain/support healthy growth and development in children

Maintain/support general health and wellbeing in children

Maintain/support healthy teeth in children

Maintain/support bone health in children

Aids/assists healthy bone development/growth/building in children

Maintain/support bone mass/density/integrity in children

Maintain/support (state mineral) absorption in bones in children

Maintain/support bone strength in children

Help maintain/support bone mineralisation in children

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life in children

Maintain/support muscle health in children

Maintain/support muscle function in children

Maintain/support muscle strength in children

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

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).

This is not an ARTG Certificate document.
The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
Visit www.tga.gov.au for contact information

Public Summary

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 can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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, chewable
Route of Administration	Oral
Visual Identification	

Active Ingredients

calcium hydrogen phosphate dihydrate	**860.59 mg**
Equivalent: phosphorus	154 mg
Equivalent: calcium	200 mg
colecalciferol	**.0075 mg**
menaquinone 7	**8.75 microgram**

Other Ingredients (Excipients)

Acacia
citric acid
colloidal anhydrous silica
d-alpha-tocopherol
Flavour
fractionated coconut oil
hypromellose
liquid glucose
magnesium stearate
maltodextrin
mannitol
silicon dioxide
sodium ascorbate
Stevia rebaudiana
xylitol

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.

This is not an ARTG Certificate document.
The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
Visit www.tga.gov.au for contact information