Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 329303 Children's Magnesium Care

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020

Australia

ARTG Start Date 31/01/2020
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.

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 Magnesium Care

Product Type Single Medicine Product Effective Date 14/11/2025

Permitted Indications

Maintain/support energy production in children

Maintain/support general health and wellbeing in children

Maintain/support healthy teeth in children

Maintain/support bone health in children

 ${\bf Aids/assists\ healthy\ bone\ development/growth/building\ in\ children}$

Help maintain/support bone mineralisation in children

Decrease/reduce/relieve muscle cramps when dietary intake is inadequate

Helps reduce occurrence of muscle cramp when dietary intake is inadequate

Maintain/support healthy muscle contraction function in children

Maintain/support muscle health in children

Maintain/support muscle function in children

Aid/assist/helps glucose/sugar/carbohydrate metabolism in children

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

Support healthy stress response in the body in children

Maintain/support brain health in children

Maintain/support nervous system health in children

Maintain/support nervous system function in children

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

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).

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

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 the table in Part 2 of Schedule 1 to this instrument are also used.

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

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased

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physical activity.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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

magnesium amino acid chelate250 mgEquivalent: magnesium50 mgmagnesium citrate194.19 mgEquivalent: magnesium30 mg

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

Flavour

magnesium stearate

sorbitol thaumatin

xylitol

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