

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 407752 Magnesium Excel

ARTG entry for Medicine Listed

 Sponsor
 McPherson's Consumer Products Pty Ltd

 Postal Address
 Locked Bag 5018, Kingsgrove, NSW, 2208

Australia

ARTG Start Date 17/04/2023

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 . Magnesium Excel

Product Type Single Medicine Product Effective Date 17/04/2023

Permitted Indications

Maintain/support physical endurance/capacity/stamina when dietary intake is inadequate

Maintain/support heat/energy production/thermogenesis

Maintain/support body electrolyte balance after exercise

Helps restore body electrolyte balance

Maintain/support bone health

Maintain/support cardiovascular system health when dietary intake is inadequate

Maintain/support healthy cardiovascular system function when dietary intake is inadequate

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

Helps reduce occurrence of muscle cramp when dietary intake is inadequate

Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate

Maintain/support healthy muscle contraction function

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Maintain/support muscle relaxation

Maintain/support muscle strength when dietary intake is inadequate

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

Maintain/support muscle performance/endurance/stamina

Aid/assist/helps glucose/sugar/carbohydrate metabolism

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

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Decrease/reduce/relieve restlessness/excess nervous energy when dietary intake is inadequate

Maintain/support nerve conduction

Maintain/support neuromuscular function

Decrease/reduce/relieve sleeplessness when dietary intake is inadequate

Maintain/support healthy sleeping patterns when dietary intake is inadequate

Decrease/reduce feelings of aggression/irritability associated with premenstrual tension

Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension

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This is not an ARTG Certificate document.



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Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension

Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

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

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

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

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

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).

Product presentation must not imply or refer to chronic fatigue syndrome.

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

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

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

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, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

magnesium amino acid chelate 300 mg Equivalent: magnesium 60 mg magnesium aspartate tetrahydrate 153.85 mg Equivalent: magnesium 10 mg magnesium citrate 388.35 mg Equivalent: magnesium 60 ma magnesium glycinate 496.45 mg Equivalent: magnesium 70 mg

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

croscarmellose sodium

hypromellose

isomalt

magnesium stearate

medium chain triglycerides

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microcrystalline cellulose rice starch

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