Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 180203 Magnesium Citrate 900

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address PO Box 3143, KIRRAWEE, NSW, 2232

Australia

ARTG Start Date 18/02/2011

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 Citrate 900

Product Type Single Medicine Product **Effective Date** 2/03/2021

Permitted Indications

Maintain/support energy production

Maintain/support general health and wellbeing

Maintain/support bone health

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support heart health

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

Maintain/support muscle health

Maintain/support muscle function

Aid/assist/helps glucose/sugar/carbohydrate metabolism

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

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

Support healthy stress response in the body

Helps reduce occurrence of mild migraines

Maintain/support nervous system health

Maintain/support nervous system function

Decrease/reduce/relieve menstrual spasms/cramps

Decrease/reduce/relieve menstruation pain/dysmenorrhoea

Decrease/reduce/relieve symptoms of premenstrual tension

Maintain/support healthy pregnancy

Indication Requirements

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

Product presentation must only refer to mild migraine.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR

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[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.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

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

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

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

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

magnesium citrate900 mgEquivalent: magnesium145.8 mg

Other Ingredients (Excipients)

hypromellose

magnesium stearate

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