Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 202122 Magnesium-Diasporal

ARTG entry for Medicine Listed

Sponsor bWellness Pty Ltd

Postal Address 651 Portrush Road, Glen Osmond, SA, 5064

Australia

ARTG Start Date 22/10/2012

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-Diasporal

Product Type Single Medicine Product Effective Date 16/10/2025

Permitted Indications

Maintain/support energy levels

Maintain/support energy production

Maintain/support body electrolyte balance

Maintain/support general health and wellbeing

Maintain/support healthy teeth

Maintain/support bone health

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support heart health

Maintain/support healthy immune system function

Decrease/reduce/relieve muscle cramps 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 (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral) within normal range

Decrease/reduce/relieve symptoms of mild anxiety

Decrease/reduce/relieve mild migraine symptoms

Maintain/support nerve conduction

Maintain/support nervous system health

Maintain/support nervous system function

Decrease/reduce/relieve menstrual spasms/cramps

Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

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Department of Health, Disability and Ageing

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

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

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 serious immunological diseases.

Product presentation must only refer to mild anxiety.

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

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

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

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 Powder, oral

Route of Administration

Oral

Visual Identification

Active Ingredients

magnesium citrate468.727 mg/gEquivalent: magnesium72.727 mg/g

Other Ingredients (Excipients)

beet red

citric acid

Flavour

potassium bicarbonate

riboflavin

Steviol glycosides

xylitol

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