

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 396678 MagDuo Berry

ARTG entry for Medicine Listed

Sponsor Biomedica Nutraceuticals Pty Ltd

Postal Address PO Box 7052, ALEXANDRIA, NSW, 2015

Australia

ARTG Start Date 29/09/2022

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. MagDuo Berry

 Product Type
 Single Medicine Product
 Effective Date
 29/09/2022

Permitted Indications

Maintain/support energy levels

Maintain/support general health and wellbeing

Maintain/support bone health

Aids/assists healthy bone development/growth/building

Antispasmodic/spasmolytic

Maintain/support healthy muscle contraction function

Maintain/support muscle health

Maintain/support muscle relaxation

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

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

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

Maintain/support nerve conduction

Aid/assist/helps synthesis of neurotransmitters

Maintain/support nervous system health

Maintain/support nervous system function

Maintain/support healthy sleeping patterns

Indication Requirements

Product presentation must not imply or refer to serious musculoskeletal or neurological 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 Table 2 of this instrument are also used.

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 mental illnesses, disorders or conditions.

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).

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

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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 citrate
 452.5 mg/g

 Equivalent: magnesium
 73.31 mg/g

 magnesium glycinate
 97.5 mg/g

 Equivalent: magnesium
 11.12 mg/g

Other Ingredients (Excipients)

Black currant

citric acid

colloidal anhydrous silica

Flavour

glycine

maltodextrin

thaumatin

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