Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 405076 Advanced Magnesium+

ARTG entry for Medicine Listed

Sponsor JSHealth Vitamins Pty Ltd

Postal Address 17 Kimberley Street, Vaucluse, NSW, 2030

Australia

ARTG Start Date 20/02/2023

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 . Advanced Magnesium+

Product Type Single Medicine Product Effective Date 20/02/2023

Permitted Indications

Helps convert (state food) into energy

Maintain/support energy production

Aids/assists teeth development

Maintain/support healthy teeth

Maintain/support bone health

Aids/assists healthy bone development/growth/building

Maintain/support bone mass/density/integrity

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 function

Maintain/support muscle relaxation

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Aid/assist/helps protein synthesis in the body

Maintain/support nervous system health

Maintain/support nervous system function

Indication Requirements

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.

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

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.

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Product presentation must not imply or refer to serious cardiovascular 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 Tablet, film coated

Route of Administration

Visual Identification **Active Ingredients**

magnesium amino acid chelate 250 mg Equivalent: magnesium 50 mg magnesium citrate 626.57 mg Equivalent: magnesium 100 mg magnesium glycinate dihydrate 434.29 mg Equivalent: magnesium 50.64 mg

Other Ingredients (Excipients)

Carnauba Wax

chlorophyllin-copper complex colloidal anhydrous silica croscarmellose sodium crospovidone

hydrogenated vegetable oil

hypromellose macrogol 400 magnesium stearate microcrystalline cellulose

povidone

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