



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375630	Hivita Wellness MAGNESIUM Aspartate
ARTG entry for	Medicine Listed	
Sponsor	Hivita Happy Energy Pty Ltd	
Postal Address	8-10 Kurrle Road, Sunbury, VIC, 3429 Australia	
ARTG Start Date	30/09/2021 11:00:00 PM	
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 . Hivita Wellness MAGNESIUM Aspartate

Product Type	Single Medicine Product	Effective Date	22/02/2022
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Permitted Indications

- Maintain/support general health and wellbeing
- Aids/assists teeth development
- Maintain/support bone health
- Helps maintain/support healthy heart function
- Maintain/support healthy cardiovascular system function
- Decrease/reduce/relieve muscle cramps
- Helps decrease/reduce/relieve mild muscle spasms/twitches
- Helps enhance/promote healthy muscle function
- Maintain/support muscle function
- Decrease/reduce/relieve muscle pain/ache/soreness
- Enhance/improve/promote/increase mind relaxation
- Decrease/reduce/relieve symptoms of stress
- Maintain/support nervous system function

Indication Requirements

- 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 serious cardiovascular conditions.
- Product presentation must not imply or refer to mental illnesses, disorders or 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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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 aspartate dihydrate	500 mg
Equivalent: magnesium	37.5 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

magnesium stearate

microcrystalline cellulose

povidone

purified water

silicon dioxide

sorbitol

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