

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 367672 Mixed Mag Forte

ARTG entry for Medicine Listed

Sponsor RN Labs Pty Ltd

Postal Address 18 / 93 Rivergate Place, MURARRIE, QLD, 4172

Australia

ARTG Start Date 1/06/2021

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. Mixed Mag Forte

Product Type Single Medicine Product Effective Date 1/06/2021

Permitted Indications

Helps enhance/promote general health and wellbeing

Aids/assists healthy bone development/growth/building

Maintain/support cardiovascular system health

Maintain/support digestion/assimilation of nutrients

Decrease/reduce/relieve muscle cramps

Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body

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

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 cardiovascular 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.

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

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Pack Size Poison Schedule

Com	noa	ents

1 . Formulation 1

Dosage FormPowderRoute of AdministrationOral

Visual Identification

Active Ingredients

 glycine
 50 mg/g

 magnesium citrate
 431.5 mg/g

 Equivalent: magnesium
 66.67 mg/g

 magnesium glycinate dihydrate
 213.68 mg/g

 Equivalent: magnesium
 25 mg/g

 magnesium orotate dihydrate
 127 mg/g

 Equivalent: magnesium
 8.33 mg/g

 taurine
 83.33 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica

Flavour

malic acid

Siraitia grosvenorii Stevia rebaudiana

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