



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	361392	Magnesium Plus
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	12/04/2021	
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 . Magnesium Plus

Product Type	Single Medicine Product	Effective Date	22/06/2022
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Permitted Indications

- Maintain/support energy levels
- Maintain/support energy levels in children
- Maintain/support energy production in children
- Maintain/support energy production
- Maintain/support body electrolyte balance
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in children
- Maintain/support healthy teeth
- Maintain/support healthy teeth in children
- Maintain/support bone health
- Maintain/support bone health in children
- Aids/assists healthy bone development/growth/building in children
- Help maintain/support bone mineralisation in children
- Help maintain/support bone mineralisation
- Aid/assist healthy red blood cell production in children
- Aid/assist healthy red blood cell production
- Maintain/support blood health in children
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Helps maintain/support haemoglobin formation/synthesis in children
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support immune system health
- Maintain/support immune system health in children
- Maintain/support healthy immune system function in children
- Maintain/support healthy immune system function

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- Maintain/support muscle function
- Maintain/support muscle function in children
- Maintain/support healthy neuromuscular system/function
- Maintain/support healthy neuromuscular system/function in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in children
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support nerve conduction in children
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters in children
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health in children
- Maintain/support nervous system health
- Maintain/support nervous system function in children
- Maintain/support nervous system function

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular 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.

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

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 serious immunological diseases.

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 chronic fatigue syndrome.

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).

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 Oral

Visual Identification

Active Ingredients

magnesium glycinate dihydrate	641.03 mg
Equivalent: magnesium	75 mg
menaquinone 7	10 microgram
pyridoxal 5-phosphate monohydrate	3.13 mg
Equivalent: pyridoxine	2 mg

Other Ingredients (Excipients)



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Acacia
ascorbyl palmitate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
glycerol
glyceryl monostearate
Guar Gum
hypromellose
lecithin
magnesium stearate
maize starch
microcrystalline cellulose
purified water
Rosmarinus officinalis

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