



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	363112	PrimerPlus
ARTG entry for	Medicine Listed	
Sponsor	Spectrumceuticals Pty Ltd	
Postal Address	10/5 Narabang Way, BELROSE, NSW, 2085 Australia	
ARTG Start Date	23/04/2021	
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 . PrimerPlus

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

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Aid/assist healthy red blood cell production
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Aid/assist/helps protein synthesis in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support cognitive function/mental function in healthy adults
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function

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- Maintain/support female reproductive system health
- Maintain/support preconception health in healthy females
- Maintain/support preconception health in healthy males
- Maintain/support reproductive system health in males
- Maintain/support healthy reproductive hormones
- Maintain/support sperm health in healthy males
- Maintain/support sperm production in healthy males
- Maintain/support testosterone level
- Maintain/support skin health
- Maintain/support skin integrity/structure
- Maintain/support wound healing

Indication Requirements

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).

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

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to infertility.

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 mental illnesses, disorders or conditions.

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).

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.

Product presentation must not imply or refer to hormone imbalances.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

magnesium glycinate dihydrate	175.44 mg
Equivalent: magnesium	20 mg
manganese gluconate	40.52 mg
Equivalent: manganese	5 mg
mixed (low-alpha type) tocopherols concentrate	50 mg
molybdenum trioxide	150 microgram



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Equivalent: molybdenum	100 microgram
pyridoxal 5-phosphate monohydrate	13.48 mg
Equivalent: pyridoxine	8.6 mg
pyridoxine hydrochloride	10 mg
Equivalent: pyridoxine	8.23 mg
zinc citrate dihydrate	77.88 mg
Equivalent: zinc	25 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
leucine
microcrystalline cellulose
potable water
potassium acetate
Rape Seed Oil

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