



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>		363112	PrimerPlus
<b>ARTG entry for</b>	Medicine Listed		
<b>Sponsor</b>	Spectrumceuticals Pty Ltd		
<b>Postal Address</b>	Unit 8/5 Narabang Way, BELROSE, NSW, 2085 Australia		
<b>ARTG Start Date</b>	23/04/2021		
<b>Product Category</b>	Medicine		
<b>Status</b>	Active		
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/12/2022
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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  
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  
Maintain/support skin health  
Maintain/support skin integrity/structure

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Maintain/support wound healing

#### Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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).

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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.

#### 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

#### Components

##### 1. Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

##### Visual Identification

##### Active Ingredients

<b>magnesium glycinate dihydrate</b>	<b>175.44 mg</b>
Equivalent: magnesium	20 mg
<b>manganese gluconate</b>	<b>40.52 mg</b>
Equivalent: manganese	5 mg
<b>mixed (low-alpha type) tocopherols concentrate</b>	<b>50 mg</b>
<b>molybdenum trioxide</b>	<b>150 microgram</b>
Equivalent: molybdenum	100 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>13.48 mg</b>
Equivalent: pyridoxine	8.6 mg
<b>pyridoxine hydrochloride</b>	<b>10 mg</b>
Equivalent: pyridoxine	8.23 mg
<b>zinc citrate dihydrate</b>	<b>77.88 mg</b>
Equivalent: zinc	25 mg

##### Other Ingredients (Excipients)

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

leucine

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microcrystalline cellulose

potable water

potassium acetate

Rape Seed Oil

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