



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	352491	Sym Balance
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Interclinical Laboratories Pty Ltd	
<b>Postal Address</b>	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	5/01/2021	
<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 . Sym Balance**

Product Type	Single Medicine Product	Effective Date	7/01/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Traditionally used in Western herbal medicine to relieve feelings of general malaise/general debility
- Maintain/support energy production
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Maintain/support cardiovascular system health
- Traditionally used in Western herbal medicine to cardi tonic/strengthen heart
- Traditionally used in Western herbal medicine to helps maintain/support healthy heart function
- Traditionally used in Western herbal medicine to maintain/support heart health
- Maintain/support heart health
- Maintain/support healthy liver function
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Aids/assists the body to cope with environmental stress
- Support healthy stress response in the body
- Traditionally used in Western herbal medicine to relieve irritability in females
- Traditionally used in Western herbal medicine to relieve irritability
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Soothe/calm nerves
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Maintain/support nerve conduction

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Aid/assist/helps synthesis of neurotransmitters  
 Maintain/support nervous system health  
 Traditionally used in Western herbal medicine to calmative/nervous system relaxant  
 Traditionally used in Western herbal medicine to nervine/support nervous system  
 Maintain/support nervous system function  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve mild nerve pain/neuralgia  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness  
 Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep

**Indication Requirements**

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 mental illnesses, disorders or conditions.  
 Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must only refer to mild nerve pain/neuralgia.  
 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 cardiovascular conditions.  
 Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.  
 Product presentation must not imply or refer to serious immunological diseases.  
 Product presentation must not imply or refer to serious musculoskeletal or neurological 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).

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Do not take while on warfarin therapy without medical advice.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Biotin</b>	<b>100 microgram</b>
<b>calcium glycinate dihydrate</b>	<b>279.33 mg</b>
Equivalent: calcium	50 mg
<b>calcium pantothenate</b>	<b>10.91 mg</b>
Equivalent: pantothenic acid	10 mg
<b>Camellia sinensis leaf Extract dry concentrate</b>	<b>25 mg</b>
Equivalent: Camellia sinensis (Dry)	250 mg
<b>choline bitartrate</b>	<b>121.57 mg</b>
Equivalent: choline	50 mg
<b>colecalfiferol</b>	<b>2 microgram</b>

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<b>copper (II) glycinate</b>	<b>1.665 mg</b>
Equivalent: copper	500 microgram
<b>hydroxocobalamin</b>	<b>100 microgram</b>
<b>Leonurus cardiaca herb Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Leonurus cardiaca (Dry)	1 g
<b>lysine hydrochloride</b>	<b>18.75 mg</b>
Equivalent: lysine	15 mg
<b>magnesium glycinate dihydrate</b>	<b>213.68 mg</b>
Equivalent: magnesium	25 mg
<b>methionine</b>	<b>15 mg</b>
<b>ornithine monohydrochloride</b>	<b>19.14 mg</b>
Equivalent: ornithine	15 mg
<b>Passiflora incarnata herb Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Passiflora incarnata (Dry)	600 mg
<b>Piper nigrum fruit Extract dry concentrate</b>	<b>12 microgram</b>
Equivalent: Piper nigrum (Dry)	300 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>3.14 mg</b>
Equivalent: pyridoxine	2 mg
<b>riboflavin</b>	<b>2 mg</b>
<b>Schisandra chinensis fruit Extract dry concentrate</b>	<b>25 mg</b>
Equivalent: Schisandra chinensis (Dry)	500 mg
<b>taurine</b>	<b>50 mg</b>
<b>ubidecarenone</b>	<b>25 mg</b>
<b>Other Ingredients (Excipients)</b>	
<b>Acacia</b>	
<b>Arthrospira platensis</b>	
<b>Carnauba Wax</b>	
<b>citric acid</b>	
<b>colloidal anhydrous silica</b>	
<b>croscarmellose sodium</b>	
<b>d-alpha-tocopherol</b>	
<b>fractionated coconut oil</b>	
<b>hypromellose</b>	
<b>hypromellose</b>	
<b>liquid glucose</b>	
<b>magnesium stearate</b>	
<b>maltodextrin</b>	
<b>microcrystalline cellulose</b>	
<b>purified water</b>	
<b>riboflavin</b>	
<b>rice starch</b>	
<b>silicified microcrystalline cellulose</b>	
<b>silicon dioxide</b>	
<b>sodium ascorbate</b>	
<b>stearic acid</b>	