



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	352491	Sym Balance
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	5/01/2021	
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 . 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 cardiogenic/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: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 Product presentation must not imply or refer to serious immunological diseases.
 Product presentation must not imply or refer to mental illnesses, disorders or 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 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 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).
 Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

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

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