Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 231018 MediHerb ThyAdren Support

ARTG entry for Medicine Listed

Sponsor Integria Healthcare Australia Pty Ltd

Postal Address PO Box 4854, EIGHT MILE PLAINS, QLD, 4113

Australia

ARTG Start Date 25/11/2014

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. MediHerb ThyAdren Support

Product Type Single Medicine Product Effective Date 27/09/2021

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Helps convert (state food) into energy

Maintain/support body metabolism/metabolic rate

Maintain/support energy production

Maintain/support general health and wellbeing

Maintain/support healthy thyroid gland function

Maintain/support healthy thyroid hormones

Maintain/support thyroid gland health

Aid/assist thyroid hormone production

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in adults

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy elderly individuals

Maintain/support (state vitamin/mineral) within normal range

Support healthy stress response in the body

Maintain/support brain/central nervous system development in healthy infants

Indication Requirements

Product presentation must not imply or refer to any thyroid related diseases.

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

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.

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.

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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 neurological conditions or developmental delays.

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

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

If symptoms persist, seek the advice of a healthcare professional.

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

For practitioner dispensing only.

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	k Size/	Poison	inf	ormatio	n
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Pack Size	Poison Schedule
Pack Size	Poison Schedule

Components

1. Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid calcium folinate	50 mg 69 microgram
Equivalent: folinic acid	50 microgram
calcium pantothenate	75 mg
Equivalent: calcium	6.3 mg
Equivalent: pantothenic acid	68.7 mg
colecalciferol	.01 mg
cyanocobalamin	1 mg
d-alpha-tocopheryl acid succinate	10 mg
nicotinamide	50 mg
potassium iodide	157 microgram

Equivalent: iodine 120 microgram pyridoxal 5-phosphate monohydrate 15.67 mg Equivalent: pyridoxine 10 mg pyridoxine hydrochloride 25 mg Equivalent: pyridoxine 20.5 ma Rehmannia glutinosa root Extract dry concentrate 66.67 mg Equivalent: Rehmannia glutinosa (Dry) 400 mg riboflavin sodium phosphate 4.11 ma Equivalent: riboflavin 3 ma

selenomethionine 125 microgram Equivalent: selenium 50 microgram

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thiamine hydrochloride50 mgtyrosine500 mgzinc ascorbate monohydrate100 mgEquivalent: ascorbic acid80.53 mgEquivalent: zinc15.1 mg

Other Ingredients (Excipients)

Acacia

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

dl-alpha-tocopherol

ethylcellulose

hyprolose

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hypromellose

iron oxide red

macrogol 8000 magnesium stearate

maize starch

medium chain triglycerides

microcrystalline cellulose

silicon dioxide

sucrose

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