



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	220200	Adhealth F
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	17/02/2014	
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 . Adhealth F

Product Type	Single Medicine Product	Effective Date	19/11/2020
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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 energy production
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support general health and wellbeing
Helps maintain/support healthy blood sugar/glucose
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Aid/assist thyroid hormone production
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral) within normal range
Support healthy stress response in the body
Maintain/support mental concentration/focus/clarity
Maintain/support cognitive function/mental function
Maintain/support nervous system health
Maintain/support nervous system function
Support healthy emotional/mood balance

Indication Requirements

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 mental illnesses, disorders or conditions.

Product presentation must not imply or refer to chronic fatigue syndrome.



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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 any thyroid related diseases.

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

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

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

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.

If symptoms persist consult your healthcare practitioner (or words to that effect).

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

ascorbic acid	40 mg
calcium pantothenate	75 mg
Equivalent: pantothenic acid	68.7 mg
chromium nicotinate	133.34 microgram
Equivalent: chromium	16 microgram
Eleutherococcus senticosus root Extract dry concentrate standardised	40 mg
Equivalent: Eleutherococcus senticosus (Dry)	600 mg
magnesium phosphate pentahydrate	48.4 mg
Equivalent: magnesium	10 mg
nicotinamide	15 mg
potassium iodide	98 microgram
Equivalent: iodine	75 microgram
pyridoxine hydrochloride	15 mg
Equivalent: pyridoxine	12.34 mg
Rehmannia glutinosa root Extract dry concentrate	50 mg
Equivalent: Rehmannia glutinosa (Dry)	300 mg
riboflavin	10 mg
selenomethionine	37.5 microgram
Equivalent: selenium	15 microgram
thiamine hydrochloride	10 mg
Equivalent: thiamine	8.91 mg
tyrosine	200 mg
Withania somnifera root Extract dry concentrate standardised	80 mg

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Equivalent: Withania somnifera (Dry)	1000 mg
zinc citrate dihydrate	9.35 mg
Equivalent: zinc	3 mg

Other Ingredients (Excipients)

alginate acid
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
hypromellose
maize starch
microcrystalline cellulose
purified water
stearic acid

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