



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|------------|
| 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 |
|---------------------|-------------------------|-----------------------|------------|

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

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.

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.

Additional Product information

Pack Size/Poison information

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| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

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|---|-------------------------|
| 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)

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

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