



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	306864	iThrive Nutrition - B ACTIVE
ARTG entry for	Medicine Listed	
Sponsor	Life Trends International Pty Ltd	
Postal Address	PO Box 6884, Baulkham Hills, NSW, 2153 Australia	
ARTG Start Date	10/07/2018	
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 . iThrive Nutrition - B ACTIVE

Product Type	Single Medicine Product	Effective Date	7/12/2020
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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 levels
- Maintain/support energy production
- Maintain/support eye health
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Aid/assist nail growth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Aid/assist healthy red blood cell production
- Helps enhance/promote red blood cell health
- Maintain/support red blood cell health
- Maintain/support blood health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Aid/assist digestion/breakdown of dietary fat
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Aid/assist/helps protein synthesis in the body
- Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support (state vitamin/mineral) within normal range

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- Support healthy stress response in the body
- Maintain/support cognitive function/mental function
- Maintain/support brain health
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support skin health
- Maintain/support wound healing

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 serious immunological diseases.

Product presentation must not imply or refer to serious cardiovascular 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.

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

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

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 not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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	300 mg
Biotin	500 microgram
calcium folinate	108.04 microgram
Equivalent: folic acid	100 microgram
calcium pantothenate	50 mg
Equivalent: pantothenic acid	45.8 mg
hydroxocobalamin	100 microgram
levomefolate calcium	434 microgram
Equivalent: levomefolic acid	400 microgram
mecobalamin	400 microgram
nicotinamide	100 mg
pyridoxal 5-phosphate monohydrate	26.83 mg
Equivalent: pyridoxine	17.11 mg
riboflavin sodium phosphate	30 mg

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Equivalent: riboflavin	21.9 mg
thiamine hydrochloride	100 mg
Equivalent: thiamine	89.2 mg
ubidecarenone	30 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate
- colloidal anhydrous silica
- disodium edetate
- gellan gum
- hypromellose
- microcrystalline cellulose
- potable water
- potassium acetate

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