



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		448090	Natural Energy
ARTG entry for	Medicine Listed		
Sponsor	Give Back Health Pty Ltd		
Postal Address	10/5 Canopus Street, Bridgeman Downs, QLD, 4035 Australia		
ARTG Start Date	8/05/2024		
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 . Natural Energy

Product Type	Single Medicine Product	Effective Date	8/05/2024
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Permitted Indications

Enhance/promote energy levels
Maintain/support energy levels
Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support general health and wellbeing
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve mild rheumatic aches and pains
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve mild joint pain/soreness
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
Traditionally used in Ayurvedic medicine to support healthy stress response in the body
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
Helps enhance/improve/promote/increase attention span
Decrease/reduce mental/cognitive fatigue
Maintain/support mental concentration/focus/clarity
Enhance/improve/promote/increase mental endurance/stamina
Maintain/support mental endurance/stamina
Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function
Enhance/improve/promote/increase mental alertness/wakefulness
Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall
Traditionally used in Ayurvedic medicine to maintain/support general mental wellbeing
Maintain/support general mental wellbeing
Traditionally used in Ayurvedic medicine to maintain/support nervous system health
Traditionally used in Ayurvedic medicine to maintain/support nervous system function
Traditionally used in Ayurvedic medicine to support healthy emotional/mood balance
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness

Indication Requirements



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

Product presentation must only refer to mild joint symptoms.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

Product presentation must only refer to mild rheumatic aches/pains.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Alpinia galanga rhizome Extract dry concentrate	150 mg
Equivalent: Alpinia galanga (Dry)	1.5 g
Withania somnifera root Extract dry concentrate	300 mg
Equivalent: Withania somnifera (Dry)	3.75 g

Other Ingredients (Excipients)

Acacia

calcium hydrogen phosphate dihydrate

chlorophyllin-copper complex

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

maltodextrin

microcrystalline cellulose

Oryza sativa

potassium acetate

purified water

silicon dioxide

sorbitan monolaurate

Sunflower Oil

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