



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	396075	RejuveGen
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	19/09/2022	
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 . RejuveGen

Product Type	Single Medicine Product	Effective Date	11/01/2023
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Permitted Indications

- Traditionally used in Western herbal medicine to maintain/support cardiovascular system health
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Traditionally used in Western herbal medicine to maintain/support heart health
- Traditionally used in Western herbal medicine to maintain/support adrenal gland health
- Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function
- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Chinese medicine to maintain/support gastrointestinal system health
- Traditionally used in Western herbal medicine to maintain/support gastrointestinal system health
- Traditionally used in Chinese medicine to maintain/support healthy gastrointestinal function
- Traditionally used in Chinese medicine to maintain/support healthy liver function
- Traditionally used in Chinese medicine to maintain/support liver health
- Traditionally used in Chinese medicine to decrease/reduce/relieve nausea
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of mild allergies
- Traditionally used in Western herbal medicine to maintain/support immune system health
- Traditionally used in Chinese medicine to maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- Traditionally used in Chinese medicine to maintain/support immune system to fight illness
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Aids/assists the body to cope with environmental stress
- Support healthy body stress recovery
- Traditionally used in Western herbal medicine to support healthy stress response in the body
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of stress



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Decrease/reduce mental/cognitive fatigue
Traditionally used in Western herbal medicine to decrease/reduce mental/cognitive fatigue
Traditionally used in Western herbal medicine to maintain/support mental concentration/focus/clarity
Traditionally used in Western herbal medicine to maintain/support mental endurance/stamina
Maintain/support cognitive function/mental function
Maintain/support cognitive function/mental function in aging individuals
Enhance/improve/promote/increase memory/recall
Maintain/support memory/mental recall in aging individuals
Maintain/support general mental wellbeing in aging individuals
Traditionally used in Western herbal medicine to support healthy emotional/mood balance
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Western herbal medicine to aphrodisiac/Enhance/improve/promote healthy libido
Traditionally used in Western herbal medicine to maintain/support healthy libido
Traditionally used in Western herbal medicine to maintain/support healthy sexual function
Traditionally used in Chinese medicine to decrease/reduce/relieve cough
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild throat infection
Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis
Traditionally used in Chinese medicine to relieve minor skin eruptions
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of boils
Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Traditionally used in Western herbal medicine to maintain/support energy levels
Maintain/support energy levels
Traditionally used in Western herbal medicine to aids/assists with recovery from illness/convalescence
Traditionally used in Western herbal medicine to relieve feelings of general malaise/general debility
Traditionally used in Western herbal medicine to maintain/support physical endurance/capacity/stamina
Maintain/support physical endurance/capacity/stamina
Maintain/support vitality
Relieve weariness/tiredness/fatigue/feeling of weakness
Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
Traditionally used in Western herbal medicine to body tonic
Traditionally used in Western herbal medicine to longevity tonic
Traditionally used in Western herbal medicine to rejuvenating tonic
Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
Maintain/support general health and wellbeing
Anti-inflammatory/relieve inflammation
Traditionally used in Chinese medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
Maintain/support healthy blood circulation

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.
Label statement: If symptoms persist, talk to your health professional.
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 not imply or refer to serious allergic conditions such as anaphylaxis.
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).
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 infections.
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to any adrenal related diseases.
Label statement: Not to be used in children under 5 years.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.



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Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to eating disorders.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not to be taken by children under 12 years old (or words to that effect).

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

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

Astragalus membranaceus root Extract dry concentrate	200 mg
Equivalent: Astragalus membranaceus (Dry)	2 g
Bacopa monnieri whole plant Extract dry concentrate standardised	200 mg
Equivalent: Bacopa monnieri (Dry)	4000 mg
nicotinamide riboside chloride	50 mg
Equivalent: ribose	25.82 mg
Panax ginseng root Extract dry concentrate	100 mg
Equivalent: Panax ginseng (Dry)	400 mg
quercetin dihydrate	125 mg
Scutellaria baicalensis root Extract dry concentrate	100 mg
Equivalent: Scutellaria baicalensis (Dry)	2 g

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- edetic acid
- gellan gum
- glucose
- hypromellose
- leucine
- maltodextrin
- microcrystalline cellulose
- potable water
- potassium acetate

Public Summary

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