

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 232094 Ki Immune Defence & Energy Formula

ARTG entry for Medicine Listed

Sponsor Martin & Pleasance Pty Ltd

Postal Address PO Box 2007, SOUTH MELBOURNE, VIC, 3205

Australia

ARTG Start Date 22/12/2014

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Ki Immune Defence & Energy Formula

 Product Type
 Single Medicine Product
 Effective Date
 29/06/2020

Permitted Indications

Traditionally used in Chinese medicine to maintain/support energy levels

Traditionally used in Chinese medicine to aids/assists with recovery from illness/convalescence

Traditionally used in Chinese medicine to relieve feelings of general malaise/general debility

Traditionally used in Chinese medicine to enhance/promote/physical endurance/capacity/stamina

Traditionally used in Chinese medicine to enhance/promote/physical endurance/capacity/stamina

Traditionally used in Chinese medicine to helps enhance/promote body energy reserves

Traditionally used in Chinese medicine to helps enhance/promote/increase vitality

Traditionally used in Chinese medicine to maintain/support vitality

Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Traditionally used in Chinese medicine to maintain/support eye health

Traditionally used in Chinese medicine to body tonic

Traditionally used in Chinese medicine to helps enhance/promote general health and wellbeing

Traditionally used in Western herbal medicine to maintain/support general health and wellbeing

Traditionally used in Chinese medicine to maintain/support healthy blood circulation

Traditionally used in Chinese medicine to blood tonic/Enhance blood health

Traditionally used in Chinese medicine to maintain/support cardiovascular system health

Traditionally used in Western herbal medicine to maintain/support cardiovascular system health

Traditionally used in Chinese medicine to maintain/support healthy appetite

Traditionally used in Chinese medicine to maintain/support healthy bowel/colon function

Traditionally used in Chinese medicine to enhance/promote healthy digestion

Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of mild allergies

Traditionally used in Chinese medicine to helps reduce occurrence of symptoms of mild allergies

Maintain/support immune system health

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Traditionally used in Chinese medicine to maintain/support immune system health

Traditionally used in Western herbal medicine to maintain/support immune system health

Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity

Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function

Helps enhance/improve/promote immune system function

Traditionally used in Chinese medicine to decrease/reduce/relieve common cold duration

Traditionally used in Chinese medicine to maintain/support skin health

Indication Requirements

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

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 serious cardiovascular conditions.

Product presentation must not imply or refer to eating disorders.

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

Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.

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

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 serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Astragalus membranaceus root Extract dry concentrate	250 mg
Equivalent: Astragalus membranaceus (Dry)	5 g
Lentinula edodes mushroom Extract dry concentrate	300 mg
Equivalent: Lentinula edodes (Dry)	3 g
Olea europaea leaf Extract dry concentrate	200 mg
Equivalent: Olea europaea (Dry)	2 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

chlorophyllin-copper complex

colloidal anhydrous silica

croscarmellose sodium

hypromellose

macrogol 400

magnesium stearate

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microcrystalline cellulose

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