



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	340989	Ki Immune Defence FORTE
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	6/08/2020	
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 FORTE

Product Type	Single Medicine Product	Effective Date	6/08/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- 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
- 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 Western herbal medicine to maintain/support cardiovascular system health
- Traditionally used in Chinese 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

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Maintain/support intestinal good/beneficial/friendly flora
Nourish good/beneficial/friendly intestinal flora
Decrease/reduce/relieve symptoms of hayfever
Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of mild allergies
Helps decrease/reduce/relieve symptoms of mild allergies
Decrease/reduce/relieve symptoms of allergic rhinitis
Helps decrease/reduce/relieve symptoms of seasonal allergies
Traditionally used in Chinese medicine to helps reduce occurrence of symptoms of mild allergies
Traditionally used in Chinese medicine to maintain/support immune system health
Traditionally used in Western herbal medicine to maintain/support immune system health
Maintain/support immune system health
Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity
Traditionally used in Western herbal 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 helps enhance/improve/promote immune system function
Traditionally used in Chinese medicine to maintain/support healthy immune system function
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function
Traditionally used in Chinese medicine to helps stimulate a healthy immune system response
Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Traditionally used in Chinese medicine to decrease/reduce/relieve common cold duration
Traditionally used in Chinese medicine to maintain/support skin health

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
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 chronic fatigue syndrome.
Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
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 cardiovascular conditions.
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).
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.
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

Do not take while on warfarin therapy without medical advice.
Adults only.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components



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1 . Formulation 1

Dosage Form Tablet, film coated
Route of Administration Oral

Visual Identification

Active Ingredients

Astragalus membranaceus	277.8292 mg
Grifola frondosa fruiting body Extract dry concentrate	21 mg
Equivalent: Grifola frondosa (Dry)	210 mg
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
zinc amino acid chelate	35 mg
Equivalent: zinc	7 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
magnesium stearate

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