



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	340989	Ki Immune Defence FORTE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Martin & Pleasance Pty Ltd	
<b>Postal Address</b>	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
<b>ARTG Start Date</b>	6/08/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 Western herbal medicine to enhance/improve/promote immune defence/immunity  
 Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity  
 Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function  
 Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function  
 Helps enhance/improve/promote immune system function  
 Maintain/support healthy immune system function  
 Traditionally used in Chinese medicine to 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**

Product presentation must not imply or refer to chronic fatigue syndrome.  
 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.  
 Label statement: If symptoms persist, talk to your health professional.  
 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 cardiovascular conditions.  
 Product presentation must not imply or refer to eating disorders.  
 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 vision correction, faults or serious eye disease e.g. macular degeneration.  
 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 mental illnesses, disorders or conditions.  
 Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

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**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Astragalus membranaceus</b>	<b>277.8292 mg</b>
<b>Grifola frondosa fruiting body Extract dry concentrate</b>	<b>21 mg</b>
Equivalent: Grifola frondosa (Dry)	210 mg
<b>Lentinula edodes mushroom Extract dry concentrate</b>	<b>300 mg</b>
Equivalent: Lentinula edodes (Dry)	3 g
<b>Olea europaea leaf Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Olea europaea (Dry)	2 g
<b>zinc amino acid chelate</b>	<b>35 mg</b>
Equivalent: zinc	7 mg

**Other Ingredients (Excipients)**

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

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