



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	387831	IMMUNE GUARD
ARTG entry for	Medicine Listed	
Sponsor	Melrose Laboratories Pty Ltd	
Postal Address	16-18 Lionel Rd, Mt Waverley, VIC, 3149 Australia	
ARTG Start Date	3/05/2022	
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 . IMMUNE GUARD

Product Type	Single Medicine Product	Effective Date	3/05/2022
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body in children over 12 years of age
- Relieve weariness/tiredness/fatigue/feeling of weakness in children over 12 years of age
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Relieve weariness/tiredness/fatigue/feeling of weakness in children over 12 years of age
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Anti-inflammatory/relieve inflammation
- Helps decrease/reduce/relieve symptoms of mild allergies
- Maintain/support immune system health
- Maintain/support healthy immune system function in children over 12 years of age
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve common cold duration in children over 12 years of age
- Decrease/reduce/relieve the severity of common cold symptoms

Indication Requirements

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

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

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 allergic conditions such as anaphylaxis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	400 mg/g
calcium ascorbate dihydrate	87.7 mg/g
Equivalent: ascorbic acid	72 mg/g
colecalfiferol	.005 mg/g
Olea europaea leaf Extract dry concentrate	40 mg/g
Equivalent: Olea europaea (Dry)	400 mg/g
quercetin dihydrate	94.25 mg/g
Equivalent: quercetin	80 mg/g
Terminalia ferdinandiana fruit flesh Powder	8 mg/g
Equivalent: Terminalia ferdinandiana (Dry)	8 mg/g
zinc citrate	12.9 mg/g
Equivalent: zinc	4 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica

dl-alpha-tocopherol

Flavour

glucose monohydrate

hydrogenated soya oil

hydrolysed gelatin

maize starch

maltodextrin

Saccharomyces cerevisiae

silicon dioxide

sucrose

thaumatin

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