



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|----------------|
| Summary for ARTG Entry: | 287643 | ImmunePro Plus |
| ARTG entry for | Medicine Listed | |
| Sponsor | Bio-Practica Pty Ltd | |
| Postal Address | 651 Portrush Road, GLEN OSMOND, SA, 5064 Australia | |
| ARTG Start Date | 7/04/2017 | |
| 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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . ImmunePro Plus

| | | | |
|---------------------|-------------------------|-----------------------|-----------------------|
| Product Type | Single Medicine Product | Effective Date | 19/11/2019 2:48:48 PM |
|---------------------|-------------------------|-----------------------|-----------------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body
- Helps enhance/promote collagen formation
- Maintain/support collagen formation
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish spleen-qi
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish lungs
- Traditionally used in Western herbal medicine to maintain/support energy levels
- Traditionally used in Western herbal medicine to maintain/support energy levels
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Maintain/support healthy eye function
- Traditionally used in Chinese medicine to decrease/reduce/relieve excessive perspiration/sweating
- Traditionally used in Western herbal medicine to restorative tonic
- Maintain/support general health and wellbeing
- Aids/assists teeth development
- Aids/assists teeth development
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support cardiovascular system health
- Traditionally used in Ayurvedic medicine to maintain/support healthy digestion

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Traditionally used in Ayurvedic medicine to maintain/support gallbladder function
Traditionally used in Ayurvedic medicine to maintain/support gallbladder function
Hepatoprotectant/protect the liver
Traditionally used in Ayurvedic medicine to maintain/support healthy liver function
Traditionally used in Ayurvedic medicine to maintain/support healthy liver function
Traditionally used in Ayurvedic medicine to maintain/support liver health
Maintain/support immune system health
Enhance/improve/promote immune defence/immunity
Helps enhance/improve/promote immune system function
Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function
Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function
Helps enhance/improve/promote immune system function
Traditionally used in Western herbal medicine to maintain/support healthy immune system function
Traditionally used in Chinese medicine to maintain/support healthy immune system function
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support nervous system function
Maintain/support sperm production
Maintain/support testosterone level
Decrease/reduce/relieve symptoms of common colds and flu
Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
Maintain/support skin health
Maintain/support skin health
Maintain/support wound healing
Maintain/support wound healing
Maintain/support skin repair/healing/regeneration
Maintain/support skin repair/healing/regeneration

Indication Requirements

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

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

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to infertility.

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 serious immunological diseases.

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.

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).

Respiratory tract infections must be qualified by 'mild'.

Product presentation must not imply or refer to disease in any body organ.

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.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Adults only. OR Not to be used in children under two years of age without medical advice (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.

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

| | |
|--|----------------|
| Andrographis paniculata leaf Extract dry concentrate | 150 mg |
| Equivalent: Andrographis paniculata (Dry) | 1.5 g |
| ascorbic acid | 250 mg |
| Astragalus membranaceus root Extract dry concentrate | 175 mg |
| Equivalent: Astragalus membranaceus (Dry) | 3.5 g |
| Lentinula edodes mushroom Extract dry concentrate | 320 mg |
| Equivalent: Lentinula edodes (Dry) | 3.2 g |
| Olea europaea leaf Extract dry concentrate standardised | 200 mg |
| Equivalent: Olea europaea (Dry) | 3.5 g |
| zinc citrate dihydrate | 32.8 mg |
| Equivalent: zinc | 10 mg |

Other Ingredients (Excipients)

- calcium hydrogen phosphate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- hypromellose
- macrogol 8000
- maltodextrin
- microcrystalline cellulose
- povidone
- stearic acid

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