



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

## Public Summary

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

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/06/2022
---------------------	-------------------------	-----------------------	------------

### 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  
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

Public Summary



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

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 helps enhance/improve/promote immune system function  
Traditionally used in Chinese medicine to maintain/support healthy immune system function  
Traditionally used in Western herbal 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 serious immunological diseases.

Label statement: If symptoms persist, talk to your health professional.

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

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

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).

Respiratory tract infections must be qualified by 'mild'.

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

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

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 infertility.

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 cardiovascular conditions.

Product presentation must not imply or refer to mental illnesses, disorders or 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

Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical advice (or words to that effect).

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (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.

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).

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

#### Additional Product information



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

**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**

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary