



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

## Public Summary

<b>Summary for ARTG Entry:</b>	225289	ImmunActiv Restore
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
<b>ARTG Start Date</b>	3/07/2014	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

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 . ImmunActiv Restore

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	18/01/2021
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### Permitted Indications

Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic  
Traditionally used in Chinese medicine to enrich/nourish/tonify/fortify/strengthen kidneys  
Traditionally used in Ayurvedic medicine to maintain/support healthy immune system function  
Traditionally used in Chinese medicine to maintain/support immune system to fight illness  
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress  
Traditionally used in Ayurvedic medicine to nervine/support nervous system  
Traditionally used in Ayurvedic medicine to soporific/induces sleep  
Traditionally used in Chinese medicine to lung tonic/Enhance lung health

### Indication Requirements

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

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

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.

Product presentation must not imply or refer to kidney disease.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

Contains lactose (or words to that effect).

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

### Additional Product information

### Pack Size/Poison information



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

Pack Size

Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Astragalus membranaceus root Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Astragalus membranaceus (Dry)	2 g
<b>Cordyceps sinensis fruiting body Extract dry concentrate</b>	<b>375 mg</b>
Equivalent: Cordyceps sinensis (Dry)	1.5 g
<b>Trametes versicolor whole plant Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Trametes versicolor (Dry)	500 mg
<b>Withania somnifera root Extract dry concentrate standardised</b>	<b>240 mg</b>
Equivalent: Withania somnifera (Dry)	3 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
chlorophyllin-copper complex  
colloidal anhydrous silica  
croscarmellose sodium  
crospovidone  
hypromellose  
macrogol 400  
magnesium stearate  
microcrystalline cellulose  
povidone

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