



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	18/01/2021
--------------	-------------------------	----------------	------------

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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

© 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