

### **Australian Government**

### **Department of Health and Aged Care**

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 299066 ImmuneForce

ARTG entry for Medicine Listed

Sponsor FIT-BioCeuticals Pty Ltd

Postal Address Blackmores Limited, PO Box 1725, Warriewood, NSW, 2102

Australia

ARTG Start Date 29/01/2018
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. ImmuneForce

Product Type Single Medicine Product Effective Date 16/08/2024

# Permitted Indications

Maintain/support immune system health

Maintain/support healthy immune system function

# Indication Requirements

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

#### 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).

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).

### Additional Product information

### Pack Size/Poison information

Pack Size Poison Schedule

# Components

#### 1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Ora

Visual Identification

### **Active Ingredients**

Andrographis paniculata leaf Extract dry concentrate standardised

142.86 mg

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# This is not an ARTG Certificate document.

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Equivalent: Andrographis paniculata (Dry) 2000.04 mg Echinacea purpurea root Extract dry concentrate standardised 166.67 mg Equivalent: Echinacea purpurea (Dry) 1 g hydrastis canadensis root Extract dry concentrate 125 mg Equivalent: hydrastis canadensis (Dry) 750 mg Inula helenium root Extract dry concentrate 100 mg Equivalent: Inula helenium (Dry) 1 g Thymus vulgaris leaf Extract dry concentrate 214.29 mg Equivalent: Thymus vulgaris (Dry) 1.5 g zinc amino acid chelate 62.5 mg Equivalent: zinc 12.5 mg

#### Other Ingredients (Excipients)

calcium carbonate

calcium hydrogen phosphate dihydrate

Carnauba Wax

chlorophyllin-copper complex colloidal anhydrous silica croscarmellose sodium

croscarmeilose sodium
crospovidone
ethylcellulose
hypromellose
macrogol 400
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose

silicon dioxide

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