Public Summary

Summary for ARTG Entry:	299066 ImmuneForce
ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	Care of Blackmores Ltd 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** 24/11/2020

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).

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	**142.86 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
crospovidone
ethylcellulose
hypromellose
macrogol 400
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose
silicon dioxide

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