

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: ImmuneForce 299066

ARTG entry for Medicine Listed

Sponsor FIT-BioCeuticals Limited

Postal Address Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102

29/01/2018 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

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 Effective Date 24/11/2020 Single Medicine Product

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)

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	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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