Public Summary

Summary for ARTG Entry:	299066 ImmuneForce
ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	PO Box 6454, ALEXANDRIA, NSW, 2015 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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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** 29/01/2018

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

1. Andrographis may reduce symptoms associated with a common cold (URTI) if taken at first stage of symptoms.
2. Andrographis has long been used in traditional Chinese medicine to clear heat and resolve fire in the lungs and throat.
3. Thyme is traditionally used in western herbal medicine to help relieve coughs due to mild upper respiratory tract infections (the common cold).
4. Thyme is traditionally used in western herbal medicine as an expectorant to reduce mild upper respiratory cattarh.
5. Golden Seal is used traditionally in western herbal medicine to assist in relieving mild dyspepsia / digestive complaints.
6. Elecampane is used traditionally in western herbal medicine as an expectorant to help relieve mild persistent coughs.
7. Zinc provides nutritional support for a healthy immune system.
8. Echinacea purpurea is traditionally used in western herbal medicine to help relieve the symptoms associated with mild upper respiratory tract infections, including the common cold, when taken at the first sign of infection.

Warnings

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

Adults only. OR Not to be used in children under two years of age without 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	Oral
Visual Identification	

Active Ingredients

Andrographis paniculata	**142.86 mg**
Echinacea purpurea	**166.67 mg**
Equivalent: Cichoric acid	1 mg
Equivalent: alkylamides (of Echinacea angustifolia and E. purpurea)	5 microgram
Equivalent: Echinacea purpurea	1 g
hydrastis canadensis	**125 mg**
Equivalent: hydrastis canadensis	750 mg
Inula helenium	**100 mg**
Equivalent: Inula helenium	1 g
Thymus vulgaris	**214.29 mg**
Equivalent: Thymus vulgaris	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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