Public Summary

Summary for ARTG Entry:	340712 ArmaForce
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	3/08/2020
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 . ArmaForce

Product Type Single Medicine Product **Effective Date** 3/08/2022

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support healthy immune system function
Decrease/reduce/relieve headache symptoms
Decrease/reduce/relieve disturbed/restless sleep
Decrease/reduce/relieve symptoms of common colds and flu
Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
Relieve symptoms of mild upper respiratory tract infections
Decrease/reduce/relieve cough
Relieve runny/dripping nose
Relieve symptoms of sore throat/pharyngitis

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to chronic fatigue syndrome.

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 serious immunological diseases.

Respiratory tract infections must be qualified by 'mild'.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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).

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (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 leaf Extract dry concentrate standardised	**178.58 mg**
Equivalent: Andrographis paniculata (Dry)	2500.12 mg
ascorbic acid	**250 mg**
Echinacea purpurea root Extract dry concentrate	**125 mg**
Equivalent: Echinacea purpurea (Dry)	750 mg
Olea europaea leaf Extract dry concentrate standardised	**150 mg**
Equivalent: Olea europaea (Dry)	750 mg
zinc amino acid chelate	**25 mg**
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

calcium carbonate
calcium hydrogen phosphate dihydrate
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose
purified talc
titanium dioxide

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