Public Summary

Summary for ARTG Entry:	315991 ArmaForce Day & Night
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	1/04/2019
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.

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.

The warning statement - Andrographis may cause taste disturbance, including loss of taste' must be displayed on the medicine label.
Any other gastrointestinal side effects listed on the label must not precede the warning related to taste disturbance and taste loss, but can be listed at the end of the required warning, or presented separately.

Products

1 . ArmaForce Day & Night

Product Type	Composite Pack	**Effective Date**	25/07/2020

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Relieve weariness/tiredness/fatigue/feeling of weakness
Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain at night time
Traditionally used in Western herbal medicine to maintain/support healthy immune system function at night time
Maintain/support healthy immune system function
Maintain/support healthy immune system function at night time
Traditionally used in Western herbal medicine to maintain/support immune system to fight illness at night time
Decrease/reduce/relieve headache symptoms
Traditionally used in Western herbal medicine to soporific/induces sleep at night time
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness at night time
Decrease/reduce/relieve disturbed/restless sleep
Decrease/reduce/relieve symptoms of common colds and flu
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu at night time
Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections at night time
Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
Relieve symptoms of mild upper respiratory tract infections
Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections at night time
Decrease/reduce/relieve cough
Relieve runny/dripping nose
Relieve symptoms of sore throat/pharyngitis

Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

Respiratory tract infections must be qualified by 'mild'.

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 serious immunological diseases.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

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	**178.58 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	**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
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone

purified talc

titanium dioxide

2 . Formulation 2

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients	
ascorbic acid	**250 mg**
Echinacea purpurea root Extract dry concentrate	**125 mg**
Equivalent: Echinacea purpurea (Dry)	750 mg
Eschscholzia californica herb Extract dry concentrate	**187.5 mg**
Equivalent: Eschscholzia californica (Dry)	750 mg
Sambucus nigra fruit Extract dry concentrate	**150 mg**
Equivalent: Sambucus nigra (Fresh)	4.8 g
Sambucus nigra flower Extract dry concentrate	**83.33 mg**
Equivalent: Sambucus nigra (Fresh)	500 mg
Scutellaria baicalensis root Extract dry concentrate	**75 mg**
Equivalent: Scutellaria baicalensis (Dry)	1.5 g

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
silicon dioxide