Public Summary

Summary for ARTG Entry:	301965	ArmaForce ImmunoBurst
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	PO Box 6454, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	18/04/2018	
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 . ArmaForce ImmunoBurst

Product Type Single Medicine Product **Effective Date** 22/06/2018

Permitted Indications

Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function

Traditionally used in Western herbal medicine to decrease/reduce/relieve common cold duration

Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections

Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of common cold symptoms

Indication Requirements

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

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

Product presentation must not imply or refer to serious immunological diseases.

Respiratory tract infections must be qualified by 'mild'.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not suitable for infants under the age of twelve months (or words to that effect).

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Echinacea purpurea	**166.665 mg**
Equivalent: Echinacea purpurea	1 g
Equivalent: Cichoric acid	50 microgram
Eucalyptus Oil	**.005 mg**
Equivalent: cineole	3.5 microgram
Honey	**25 mg**
Lemon Oil	**650 microgram**
Equivalent: Oxedrine	1 microgram
Peppermint Oil	**100 microgram**
Equivalent: menthol (of Peppermint oil)	42.5 microgram

Other Ingredients (Excipients)

caramel
Flavour
Gelatin
glycerol
glyceryl monostearate
lecithin
maltodextrin
medium chain triglycerides
menthol
microcrystalline cellulose
Orange Oil
purified water
Siraitia grosvenorii
xylitol

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