



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	355994	ArmaForce ImmunoBurst
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
ARTG Start Date	2/03/2021	
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 ImmunoBurst

Product Type	Single Medicine Product	Effective Date	3/08/2022
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Permitted Indications

- Traditionally used in Western herbal medicine to maintain/support immune system health
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
 - Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
 - Linked indication - Decongestant/relieve nasal congestion
 - Linked indication - Relieve runny/dripping nose
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections

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).
- 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.
- Product presentation must not imply or refer to serious immunological diseases.
- Label statement: Not to be used in children under 5 years.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

Public Summary



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1 . Formulation 1

Dosage Form Capsule, soft
Route of Administration Oral

Visual Identification

Active Ingredients

Echinacea purpurea root Extract dry concentrate standardised	167 mg
Equivalent: Echinacea purpurea (Dry)	1 g
Eucalyptus Oil	5 microgram
Glycyrrhiza glabra root and stolon Extract dry concentrate	5 mg
Equivalent: Glycyrrhiza glabra (Dry)	25 mg
Lemon Oil	650 microgram
Peppermint Oil	100 microgram

Other Ingredients (Excipients)

Acacia
caramel
citric acid
colloidal anhydrous silica
Flavour
Gelatin
glycerol
glyceryl monostearate
hydrogenated vegetable oil
lecithin
maltodextrin
medium chain triglycerides
menthol
Orange Oil
Peppermint Oil
potato starch
purified water
Soya Oil
thaumatin
xylitol

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