



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	355994	ArmaForce ImmunoBurst
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
<b>ARTG Start Date</b>	2/03/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

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

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components



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**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

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

**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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