



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

## Public Summary

<b>Summary for ARTG Entry:</b>	357137	ArmaForce Daily Protect
<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>	22/03/2021	
<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 Daily Protect

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	17/08/2021
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support immune system health
- Maintain/support immune system health after exercise
- Enhance/improve/promote immune defence/immunity after exercise
- Maintain/support healthy immune system function after exercise
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support immune system to fight illness after exercise
- Helps stimulate a healthy immune system response
- Helps stimulate a healthy immune system response after exercise
- Decrease/reduce/relieve common cold duration
- Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract

### Indication Requirements

- Product presentation must not imply or refer to serious immunological diseases.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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**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**

<b>ascorbic acid</b>	<b>200 mg</b>
<b>colecalfiferol</b>	<b>.0093 mg</b>
<b>Saccharomyces cerevisiae cell wall Extract dry concentrate</b>	<b>125 mg</b>
Equivalent: Saccharomyces cerevisiae	625 mg
<b>selenomethionine</b>	<b>125 microgram</b>
Equivalent: selenium	50 microgram
<b>zinc amino acid chelate</b>	<b>60 mg</b>
Equivalent: zinc	12 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
chlorophyllin-copper complex  
colloidal anhydrous silica  
croscarmellose sodium  
dl-alpha-tocopherol  
hydrogenated soya oil  
hydrolysed gelatin  
hypromellose  
macrogol 3350  
magnesium stearate  
maize starch  
microcrystalline cellulose  
silicon dioxide  
sucrose

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