



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

## Public Summary

<b>Summary for ARTG Entry:</b>	300144	ArmaForce Cough Relief
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	28/02/2018	
<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 Cough Relief

Product Type	Single Medicine Product	Effective Date	21/12/2020
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### Permitted Indications

- Traditionally used in Western herbal medicine to soothe/relieve mouth/oral irritation in children
- Traditionally used in Western herbal medicine to soothe/relieve mouth/oral irritation
- Maintain/support immune system health
- Maintain/support immune system health in children
- Maintain/support healthy immune system function in children
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion in children
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous in children
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve cough in children
- Traditionally used in Western herbal medicine to relieve dry unproductive cough in children
- Traditionally used in Western herbal medicine to relieve dry unproductive cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve throat irritation in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve throat irritation

### Indication Requirements

- 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.
- Product presentation must only refer to mild bronchitis.
- Product presentation must not imply or refer to serious immunological diseases.
- Respiratory tract infections must be qualified by 'mild'.

### Standard Indications



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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).

Adults only. OR Not to be used in children under two years of age without medical advice (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].

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Althaea officinalis root Extract dry concentrate</b>	<b>75 mg/mL</b>
Equivalent: Althaea officinalis (Dry)	300 mg/mL
<b>Echinacea purpurea root Extract dry concentrate standardised</b>	<b>16.67 mg/mL</b>
Equivalent: Echinacea purpurea (Dry)	100 mg/mL
<b>Hedera helix leaf Extract dry concentrate standardised</b>	<b>3.8 mg/mL</b>
Equivalent: Hedera helix (Dry)	22.8 mg/mL
<b>Inula helenium root Extract dry concentrate</b>	<b>15 mg/mL</b>
Equivalent: Inula helenium (Dry)	150 mg/mL
<b>Thymus vulgaris leaf Extract dry concentrate</b>	<b>14.2857 mg/mL</b>
Equivalent: Thymus vulgaris (Dry)	100 mg/mL
<b>Verbascum thapsus leaf Extract dry concentrate</b>	<b>25 mg/mL</b>
Equivalent: Verbascum thapsus (Dry)	100 mg/mL
<b>zinc gluconate</b>	<b>3.828 mg/mL</b>
Equivalent: zinc	.5 mg/mL

**Other Ingredients (Excipients)**

colloidal anhydrous silica

Honey

potassium sorbate

purified water

xanthan gum

Public Summary

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