



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	330171	ArmaForce Throat Relief
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	19/02/2020	
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.

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 Throat Relief

Product Type	Single Medicine Product	Effective Date	24/02/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support healthy immune system function

Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild throat inflammation

Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis

Indication Requirements

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.

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 immunological diseases.

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].

Contains ethanol or contains alcohol.

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.

If symptoms persist consult your healthcare practitioner (or words to that effect).



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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

Clove Bud Oil	1.3 microgram/mL
Echinacea purpurea root Extract dry concentrate standardised	28.92 mg/mL
Equivalent: Echinacea purpurea (Dry)	173.52 mg/mL
Glycyrrhiza glabra root and stolon Extract dry concentrate standardised	65.1 mg/mL
Equivalent: Glycyrrhiza glabra (Dry)	260.42 mg/mL
Honey	65.1 mg/mL
Salvia officinalis leaf Extract dry concentrate standardised	31.55 mg/mL
Equivalent: Salvia officinalis (Dry)	173.52 mg/mL
zinc gluconate	15.95 mg/mL
Equivalent: zinc	2.04 mg/mL

Other Ingredients (Excipients)

ethanol
maltodextrin
menthol
potassium sorbate
purified water
silicon dioxide
Steviol glycosides

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