

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 367676 ArmaForce for Juniors

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 1/06/2021
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 for Juniors

Product Type Single Medicine Product Effective Date 3/03/2022

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration

Maintain/support immune system health

Maintain/support healthy immune system function

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Decrease/reduce/relieve common cold duration

 $\label{lem:helps} \mbox{Helps decrease/reduce/relieve the severity of symptoms of common colds and flu}$

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu

Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis

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

Maintain/support wound healing

Indication Requirements

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

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).

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

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Therapeutic Goods Administration

Pack	Size	/Poison	inf	ormation

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormPowderRoute of AdministrationOral

Visual Identification

Active Ingredients

ascorbic acid 80 mg/g
Echinacea purpurea root Extract dry concentrate standardised 50 mg/g
Equivalent: Echinacea purpurea (Dry) 300 mg/g
quercetin dihydrate 40 mg/g

retinol acetate35.3843 microgram/gEquivalent: vitamin A29.9997 microgram/g

 Sambucus nigra fruit Extract dry concentrate standardised
 2 mg/g

 Equivalent: Sambucus nigra (Dry)
 100 mg/g

 Sambucus nigra flower Extract dry concentrate
 66.67 mg/g

Equivalent: Sambucus nigra (Dry)

zinc amino acid chelate

Equivalent: zinc

1 mg/g

Other Ingredients (Excipients)

Acacia

colloidal anhydrous silica dl-alpha-tocopherol

Flavour

Fragaria vesca

inulin

maize starch maltodextrin

spray-dried glucose syrup

Steviol glycosides

Water melon

xylitol

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