



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	212335	AndroForce
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	18/07/2013	
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 . AndroForce

Product Type	Single Medicine Product	Effective Date	9/03/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Ayurvedic medicine to vrishya/aphrodisiac/Increase in virility
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Ayurvedic medicine to maintain/support energy levels
- Maintain/support energy levels
- Maintain/support physical endurance/capacity/stamina
- Maintain/support hair health
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Enhance/promote body adaptation to stress
- Support healthy stress response in the body
- Decrease/reduce/relieve symptoms of stress
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Ayurvedic medicine to nervine/support nervous system
- Maintain/support reproductive system health in males
- Maintain/support healthy sexual function in males
- Traditionally used in Ayurvedic medicine to maintain/support healthy sexual function in males
- Maintain/support healthy sexual function when dietary intake is inadequate in males
- Helps maintain/support testosterone formation/synthesis in males
- Helps maintain/support testosterone formation/synthesis
- Maintain/support sperm health
- Maintain/support sperm motility
- Maintain/support sperm production
- Maintain/support testosterone level

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Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to infertility.
 If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains lactose (or words to that effect).
 Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
 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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

levocarnitine	50 mg
Panax ginseng root Extract dry concentrate standardised	75 mg
Equivalent: Panax ginseng (Dry)	750 mg
Pinus pinaster stem bark outer Extract dry concentrate	30 mg
Equivalent: Pinus pinaster (Dry)	30 g
selenomethionine	62.1 microgram
Equivalent: selenium	25 microgram
Tribulus terrestris herb Extract dry concentrate standardised	90.91 mg
Equivalent: furostanol saponins calc as protodioscin (of Tribulus terrestris) ()	40.9095 mg
Turnera diffusa leaf Extract dry concentrate	50 mg
Equivalent: Turnera diffusa (Dry)	500 mg
Withania somnifera root Extract dry concentrate	337.5 mg
Equivalent: Withania somnifera (Dry)	4.2187 g
zinc amino acid chelate	37.5 mg
Equivalent: zinc	7.5 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
 Carnuba Wax
 chlorophyllin-copper complex
 colloidal anhydrous silica
 croscarmellose sodium
 crospovidone



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ethylcellulose
hypromellose
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
titanium dioxide

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