



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

## Public Summary

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 when dietary intake is inadequate in males  
Maintain/support healthy sexual function in males  
Traditionally used in Ayurvedic medicine to maintain/support healthy sexual function 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 only refer to mild anxiety.

Product presentation must not imply or refer to chronic fatigue syndrome.

Label statement: If symptoms persist, talk to your health professional.

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.

Product presentation must not imply or refer to infertility.

#### 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

#### Components

##### 1 . Formulation 1

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

##### Visual Identification

#### Active Ingredients

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

#### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba 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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