



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	192213	METAGENICS ANDROLIFT
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	18/11/2011	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . METAGENICS ANDROLIFT

Product Type	Single Medicine Product	Effective Date	12/02/2020
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Permitted Indications

- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to maintain/support healthy adrenal gland function
- Traditionally used in Chinese medicine to adaptogen/Help body adapt to stress
- Traditionally used in Chinese medicine to support healthy stress response in the body
- Traditionally used in Chinese medicine to relieve irritability in/of Liver Qi Stagnation pattern
- Traditionally used in Chinese medicine to relieve irritability
- Traditionally used in Chinese medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Chinese medicine to decrease/reduce/relieve nervous tension/unrest in/of Liver Qi Stagnation pattern
- Traditionally used in Chinese medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms
- Traditionally used in Chinese medicine to support healthy emotional/mood balance in/of Liver Qi Stagnation pattern
- Traditionally used in Chinese medicine to support healthy emotional/mood balance
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Chinese medicine to maintain/support reproductive system health
- Traditionally used in Chinese medicine to male tonic

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to any adrenal related diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bupleurum falcatum root Extract dry concentrate	50 mg
Equivalent: Bupleurum falcatum (Dry)	500 mg
Citrus aurantium fruit Extract dry concentrate	50 mg
Equivalent: Citrus aurantium (Dry)	500 mg
Citrus reticulata fruit peel Extract dry concentrate	50 mg
Equivalent: Citrus reticulata (Dry)	500 mg
Cyperus rotundus rhizome Extract dry concentrate	100 mg
Equivalent: Cyperus rotundus (Dry)	1 g
Glycyrrhiza uralensis root and rhizome Extract dry concentrate	33.3 mg
Equivalent: Glycyrrhiza uralensis (Dry)	333 mg
Ligusticum striatum rhizome Extract dry concentrate	33.3 mg
Equivalent: Ligusticum striatum (Dry)	333 mg
Paeonia lactiflora root Extract dry concentrate	50 mg
Equivalent: Paeonia lactiflora (Dry)	500 mg
Panax ginseng root Extract dry concentrate	33.3 mg
Equivalent: Panax ginseng (Dry)	333 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- disodium edetate
- gellan gum
- hypromellose
- magnesium stearate
- microcrystalline cellulose
- potable water
- potassium acetate
- silicon dioxide

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