



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|------------------------------------|
| Summary for ARTG Entry: | 226549 | METAGENICS TRIBULUS SYNERGY T-LIFT |
| ARTG entry for | Medicine Listed | |
| Sponsor | Metagenics (Aust) Pty Ltd | |
| Postal Address | PO Box 675, VIRGINIA BC, QLD, 4014 Australia | |
| ARTG Start Date | 4/08/2014 | |
| 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 . METAGENICS TRIBULUS SYNERGY T-LIFT

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 5/05/2020 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

- Traditionally used in Chinese medicine to help enhance/promote/increase vitality
- Maintain/support reproductive system health in healthy males
- Maintain/support reproductive system health
- Traditionally used in Ayurvedic medicine to maintain/support reproductive system health in healthy males
- Traditionally used in Ayurvedic medicine to maintain/support healthy libido
- Traditionally used in Ayurvedic medicine to maintain/support healthy sexual function
- Traditionally used in Mexican herbal medicine to/as maintain/support healthy sexual function
- Traditionally used in Chinese medicine to maintain/support healthy sexual function in healthy males
- Traditionally used in Chinese medicine to maintain/support healthy sexual function
- Traditionally used in Ayurvedic medicine to male tonic

Indication Requirements

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

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).
- 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.

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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

| | |
|--|------------------|
| Epimedium sagittatum herb top Extract dry concentrate | 100 mg |
| Equivalent: Epimedium sagittatum (Dry) | 1.5 g |
| Nelumbo nucifera seed Extract dry concentrate | 300 mg |
| Equivalent: Nelumbo nucifera (Dry) | 1.5 g |
| Tribulus terrestris fruit Extract dry concentrate | 333.33 mg |
| Equivalent: Tribulus terrestris (Dry) | 5 g |
| Turnera diffusa leaf Extract dry concentrate | 333.33 mg |
| Equivalent: Turnera diffusa (Dry) | 2 g |
| zinc amino acid chelate | 30 mg |
| Equivalent: zinc | 6 mg |

Other Ingredients (Excipients)

carrageenan

citric acid

colloidal anhydrous silica

croscarmellose sodium

hypromellose

macrogol 8000

magnesium stearate

maltodextrin

microcrystalline cellulose

silicon dioxide

stearic acid

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