



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|------------|
| Summary for ARTG Entry: | 299403 | ThyRestore |
| ARTG entry for | Medicine Listed | |
| Sponsor | Biomedica Nutraceuticals Pty Ltd | |
| Postal Address | PO Box 7052, ALEXANDRIA, NSW, 2015 Australia | |
| ARTG Start Date | 7/02/2018 | |
| 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 . ThyRestore

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 26/03/2021 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support general health and wellbeing
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Aid/assist thyroid hormone production
Maintain/support immune system health
Maintain/support healthy immune system function

Indication Requirements

Product presentation must not imply or refer to any thyroid related diseases.
Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.
If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.
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.
WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Additional Product information

Public Summary



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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--|------------------------|
| colecalfiferol | 12.5 microgram |
| potassium iodide | 196 microgram |
| Equivalent: iodine | 149.84 microgram |
| retinol acetate | 344.1 microgram |
| Equivalent: vitamin A | 300 RE |
| selenomethionine | 186.5 microgram |
| Equivalent: selenium | 74.6 microgram |
| tyrosine | 350 mg |
| Withania somnifera root Extract dry concentrate | 300 mg |
| Equivalent: Withania somnifera (Dry) | 3.75 g |
| zinc citrate dihydrate | 31.15 mg |
| Equivalent: zinc | 10 mg |

Other Ingredients (Excipients)

Acacia
chlorophyllin-copper complex
colloidal anhydrous silica
dl-alpha-tocopherol
hypromellose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
purified water
sucrose

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