



Australian Government
Department of Health and Aged Care
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	18/03/2025
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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

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

Additional Product information



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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		
medium chain triglycerides		
microcrystalline cellulose		
purified water		
spray-dried glucose syrup		
sucrose		

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