



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	298327	Thyroplex
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	8/01/2018	
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.

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 . Thyroplex

Product Type	Single Medicine Product	Effective Date	20/01/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Aid/assist thyroid hormone production
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.

Not recommended for use by pregnant and lactating women (or words to that effect).

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.



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Adults only.

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

ascorbic acid	50 mg
Bupleurum falcatum root Extract dry concentrate	50 mg
Equivalent: Bupleurum falcatum (Dry)	500 mg
colecalfiferol	.0075 mg
d-alpha-tocopheryl acid succinate	10.33 mg
glutathione	25 mg
potassium iodide	190 microgram
Equivalent: iodine	145 microgram
retinol acetate	.4312 mg
Schisandra chinensis fruit Extract dry concentrate	187.5 mg
Equivalent: Schisandra chinensis (Dry)	750 mg
selenomethionine	186 microgram
Equivalent: selenium	75 microgram
tyrosine	500 mg
zinc amino acid chelate	50 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

- Acacia
- butylated hydroxytoluene
- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- chlorophyllin-copper complex
- croscarmellose sodium
- crospovidone
- dl-alpha-tocopherol
- ethylcellulose
- Gelatin
- hypromellose
- macrogol 8000
- magnesium stearate
- maize starch
- maltodextrin
- medium chain triglycerides
- microcrystalline cellulose
- povidone
- silicon dioxide
- sucrose

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