



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	328989	Mediherb ThyroCo
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	21/01/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Mediherb ThyroCo

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/02/2021
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#### Permitted Indications

Maintain/support body metabolism/metabolic rate  
Maintain/support general health and wellbeing  
Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Maintain/support thyroid gland health  
Aid/assist thyroid hormone production  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Maintain/support (state vitamin/mineral) within normal range

#### Indication Requirements

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

If symptoms persist, seek the advice of a healthcare professional.

For practitioner dispensing only.

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.

#### Additional Product information



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**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**

<b>Bacopa monnieri herb Extract dry concentrate standardised</b>	<b>20 mg</b>
Equivalent: Bacopa monnieri (Dry)	1 g
<b>Fucus vesiculosus whole plant Extract dry concentrate standardised</b>	<b>150 mg</b>
Equivalent: Fucus vesiculosus (Dry)	750 mg
<b>Withania somnifera root Extract dry concentrate</b>	<b>60 mg</b>
Equivalent: Withania somnifera (Dry)	600 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

sodium starch glycollate

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