



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

## Public Summary

<b>Summary for ARTG Entry:</b>	223669	MediHerb Gluco Support Complex
<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>	21/05/2014	
<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.

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 . MediHerb Gluco Support Complex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	21/08/2019
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral) within normal range

#### Indication Requirements

- Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
- 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 and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
- If product is indicated for supplementation, Label statement: 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.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications



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No Specific Indications included on Record

**Warnings**

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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

For practitioner dispensing only.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

This product 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 - this medication may be dangerous when used in large amounts or for a long time; or WARNING - this product contains [insert pyridoxine hydrochloride or pyridoxal 5-phosphate as applicable], which may be dangerous when used in large amounts or for a long time.

**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**

<b>calcium pantothenate</b>	<b>100 mg</b>
Equivalent: pantothenic acid	91.61 mg
<b>chromic chloride hexahydrate</b>	<b>1.07 mg</b>
Equivalent: chromium	209 microgram
<b>chromium nicotinate</b>	<b>116.67 microgram</b>
Equivalent: chromium	14 microgram
<b>cyanocobalamin</b>	<b>.15 mg</b>
<b>Gymnema sylvestre</b>	<b>200 mg</b>
<b>magnesium phosphate pentahydrate</b>	<b>106.49 mg</b>
Equivalent: magnesium	22 mg
<b>manganese amino acid chelate</b>	<b>20 mg</b>
Equivalent: manganese	2 mg
<b>nicotinamide</b>	<b>50 mg</b>
<b>nicotinic acid</b>	<b>20 mg</b>
<b>pyridoxine hydrochloride</b>	<b>50 mg</b>
Equivalent: pyridoxine	41.14 mg
<b>selenomethionine</b>	<b>19.87 microgram</b>
Equivalent: selenium	8 microgram
<b>zinc gluconate</b>	<b>114.85 mg</b>
Equivalent: zinc	15 mg

**Other Ingredients (Excipients)**

**calcium hydrogen phosphate dihydrate**  
**Carnauba Wax**  
**colloidal anhydrous silica**  
**crospovidone**  
**hypromellose**  
**macrogol 400**

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magnesium stearate  
mannitol  
microcrystalline cellulose  
povidone

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