



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

## Public Summary

<b>Summary for ARTG Entry:</b>	361976	HashiComplex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	14/04/2021	
<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 . HashiComplex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	26/05/2021
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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 healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Maintain/support thyroid gland health  
Aid/assist thyroid hormone production  
Maintain/support healthy immune system function  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Maintain/support female reproductive system health  
Maintain/support sperm health

#### Indication Requirements

Product presentation must not imply or refer to infertility.  
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.

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

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.



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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).

**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>colecalfiferol</b>	<b>.0062 mg</b>
<b>Hemidesmus indicus root Extract dry concentrate</b>	<b>46.88 mg</b>
Equivalent: Hemidesmus indicus (Dry)	375 mg
<b>inositol</b>	<b>150 mg</b>
<b>Nigella sativa seed Powder</b>	<b>500 mg</b>
Equivalent: Nigella sativa (Dry)	500 mg
<b>retinol acetate</b>	<b>143.38 microgram</b>
Equivalent: vitamin A	125 RE/microgram
<b>selenomethionine</b>	<b>93.1 microgram</b>
Equivalent: selenium	37.5 microgram
<b>zinc amino acid chelate</b>	<b>37.5 mg</b>
Equivalent: zinc	7.5 mg

**Other Ingredients (Excipients)**

**Acacia**  
**butylated hydroxytoluene**  
**calcium hydrogen phosphate dihydrate**  
**Carnauba Wax**  
**colloidal anhydrous silica**  
**croscarmellose sodium**  
**crospovidone**  
**dl-alpha-tocopherol**  
**hypromellose**  
**macrogol 400**  
**magnesium stearate**  
**maize starch**  
**maltodextrin**  
**medium chain triglycerides**  
**microcrystalline cellulose**  
**povidone**  
**silicon dioxide**  
**sucrose**

Public Summary

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