



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

## Public Summary

<b>Summary for ARTG Entry:</b>	370566	Saffron + Zinc
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Give Back Health Pty Ltd	
<b>Postal Address</b>	10/5 Canopus Street, Bridgeman Downs, QLD, 4035 Australia	
<b>ARTG Start Date</b>	5/07/2021	
<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 . Saffron + Zinc

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/07/2021
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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 eye function  
Maintain/support eye health  
Maintain/support healthy growth and development  
Maintain/support general health and wellbeing  
Maintain/support smell sensation  
Maintain/support taste sensation  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Aid/assist/helps protein synthesis in the body  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Help maintain/support emotional wellbeing  
Decrease/reduce/relieve symptoms of stress  
Helps reduce occurrence of symptoms of mild anxiety  
Maintain/support nervous system health  
Maintain/support nervous system function  
Support healthy emotional/mood balance  
Enhance/promote/increase refreshing sleep  
Maintain/support female reproductive system health  
Maintain/support/regulate healthy menstrual cycle  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones  
Maintain/support sperm production

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Maintain/support skin health  
 Maintain/support skin integrity/structure  
 Maintain/support wound healing in healthy individuals  
 Maintain/support skin repair/healing/regeneration in healthy individuals

**Indication Requirements**

Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.  
 Product presentation must not imply or refer to serious immunological diseases.  
 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 mental illnesses, disorders or conditions.  
 Product presentation must not imply or refer to infertility.  
 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 only refer to mild anxiety.  
 Product presentation must not imply or refer to hormone imbalances.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

1 . Formulation 1

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Crocus sativus stigma Extract dry concentrate</b>	<b>14 mg</b>
Equivalent: Crocus sativus (Dry)	42 mg
<b>zinc citrate dihydrate</b>	<b>15.58 mg</b>
Equivalent: zinc	5 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate  
 colloidal anhydrous silica  
 dextrin  
 hypromellose  
 leucine  
 microcrystalline cellulose  
 purified water

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