



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	307048	Gemmune I.B.
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Cell-Logic Pty Ltd	
<b>Postal Address</b>	ROSS COURT CENTRAL, 132-140, Cleveland, QLD, 4163 Australia	
<b>ARTG Start Date</b>	16/07/2018	
<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 . Gemmune I.B.**

Product Type	Single Medicine Product	Effective Date	16/07/2018
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Maintain/support healthy blood circulation
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support cardiovascular system health
- Helps maintain/support vasodilator/ blood vessel dilation
- Maintain/support blood vessel health
- Decrease/reduce/relieve aching/tired legs/leg heaviness associated with mild varicose veins
- Decrease/reduce/relieve leg swelling associated mild varicose veins
- Aid/assist fat distribution and assimilation in the digestive system after eating
- Aid/assist digestion of glucose/sugar/carbohydrates
- Maintain/support immune system health
- Enhance/improve/promote immune defence/immunity
- Helps enhance/improve/promote immune system function
- Maintain/support immune system to fight illness
- Helps stimulate a healthy immune system response
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Enhance/improve/promote/increase cognitive performance

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Maintain/support cognitive function/mental function  
 Maintain/support/regulate healthy menstrual cycle

**Indication Requirements**

Product presentation must not imply or refer to serious immunological diseases.  
 Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.  
 Product presentation must not imply or refer to serious cardiovascular conditions.  
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
 Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.  
 Product presentation must only refer to mild varicose veins.  
 Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

**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).

**Additional Product information**

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Citrus bioflavonoids extract</b>	<b>250 mg</b>
<b>Fucus vesiculosus whole plant Extract dry concentrate</b>	<b>60 mg</b>
Equivalent: Fucus vesiculosus (Dry)	720 mg
<b>Lactobacillus plantarum</b>	<b>5 mg</b>
<b>Vitis vinifera seed Extract dry concentrate</b>	<b>300 mg</b>
Equivalent: Vitis vinifera (Dry)	6.3 g

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
 dextrin  
 disodium edetate  
 gellan gum  
 hypromellose  
 magnesium stearate  
 maltodextrin  
 microcrystalline cellulose  
 potable water  
 potassium acetate

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