Public Summary

Summary for ARTG Entry:	307048 Gemmune I.B.
ARTG entry for	Medicine Listed
Sponsor	Cell-Logic Pty Ltd
Postal Address	ROSS COURT CENTRAL, 132-140, Cleveland, QLD, 4163 Australia
ARTG Start Date	16/07/2018
Product Category	Medicine
Status	Active
Approval Area	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

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

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 serious cardiovascular conditions.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

Product presentation must only refer to mild varicose veins.

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

Citrus bioflavonoids extract	**250 mg**
Fucus vesiculosus whole plant Extract dry concentrate	**60 mg**
Equivalent: Fucus vesiculosus (Dry)	720 mg
Lactobacillus plantarum	**5 mg**
Vitis vinifera seed Extract dry concentrate	**300 mg**
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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