Public Summary

Summary for ARTG Entry:	307053	Gemmune M.M.
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 M.M.

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

Maintain/support bone mass/density/integrity

Maintain/support healthy blood circulation

Helps in the maintenance of healthy blood lipids/blood fats

Helps maintain/support healthy cholesterol

Helps maintain/support healthy blood sugar/glucose

Maintain/support blood vessel health

Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid after eating

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Indication Requirements

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

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 not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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 cholesterol levels from outside of the normal healthy range

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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 aurantium fruit juice Extract dry concentrate	**300 mg**
Equivalent: Citrus aurantium (Dry)	51 g
Olea europaea leaf Extract dry concentrate	**260 mg**
Equivalent: Olea europaea (Dry)	3.25 g
Portulaca oleracea herb Extract dry concentrate	**90 mg**
Equivalent: Portulaca oleracea (Dry)	405 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
polysorbate 20
potable water
potassium acetate
silicon dioxide

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