Public Summary

Summary for ARTG Entry:	294624	GeneActiv Formulation C
ARTG entry for	Medicine Listed	
Sponsor	Cell-Logic Pty Ltd	
Postal Address	ROSS COURT CENTRAL, 132-140, Cleveland, QLD, 4163 Australia	
ARTG Start Date	4/10/2017	
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 . GeneActiv Formulation C

Product Type	Single Medicine Product	**Effective Date**	5/09/2019

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps enhance/promote general health and wellbeing
Maintain/support general health and wellbeing
Aids/assists teeth development
Maintain/support healthy teeth
Maintain/support teeth mineralisation
Maintain/support bone health
Aids/assists healthy bone development/growth/building
Maintain/support bone mass/density/integrity
Maintain/support bone strength
Help maintain/support bone mineralisation
Helps enhance/promote/increase metabolism of (state mineral) in bones
Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
Maintain/support healthy blood circulation
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Helps enhance/promote artery health
Maintain/support artery health

Maintain/support blood vessel health

Helps enhance/promote blood vessel health

Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body

Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

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)

Maintain/support (state vitamin/mineral) within normal range

Helps enhance/promote/increase body utilisation of (state mineral/vitamin/nutrient)

Maintain/support mental concentration/focus/clarity

Enhance/improve/promote/increase cognitive performance

Maintain/support cognitive function/mental function

Enhance/improve/promote/increase memory/recall

Maintain/support memory/mental recall

Maintain/support brain function

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

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

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 circulatory disorders/diseases/conditions e.g. thrombosis.

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.

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).

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

'Contains gluten (or words to that effect)'

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

Brassica oleracea var. italica sprout Powder	**100 mg**
Equivalent: Brassica oleracea var. italica (Dry)	100 mg
colecalciferol	**.0125 mg**
menaquinone 7	**90 microgram**
Withania somnifera root Extract dry concentrate	**125 mg**
Equivalent: Withania somnifera (Dry)	625 mg

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Withania somnifera leaf Extract dry concentrate	**125 mg**
Equivalent: Withania somnifera (Dry)	625 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
dl-alpha-tocopherol
hydrogenated soya oil
hydrolysed gelatin
hypromellose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
purified talc
purified water
silicon dioxide
sucrose