



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	294629	GeneActiv Formulation P
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 P

Product Type	Effective Date
Single Medicine Product	4/09/2019

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Aids/assists natural body cleansing/detoxification processes
- Maintain/support natural body cleansing/detoxification processes
- Maintain/support natural cleansing/detoxification processes of the gastrointestinal system/gut
- Maintain/support natural liver cleansing/detoxification processes
- Helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support blood vessel health
- Maintain/support healthy thyroid gland function
- Maintain/support immune system health
- Enhance/improve/promote immune defence/immunity
- Helps enhance/improve/promote immune system function
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support healthy gastrointestinal immune function
- Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body

Public Summary



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Maintain/support (state vitamin/mineral/nutrient) levels in the body
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Maintain/support (state vitamin/mineral) within normal range
 Aids/assists the body to cope with environmental stress
 Maintain/support female reproductive system health
 Maintain/support reproductive system health
 Help maintain/support healthy prostate function
 Helps enhance/promote prostate health
 Maintain/support prostate health

Indication Requirements

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 serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.
 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 drugs/alcohol.
 Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
 Product presentation must only refer to detoxification in relation to natural body processes.
 Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 Product presentation must not imply or refer to serious immunological diseases.
 Product presentation must not imply or refer to infertility.
 Product presentation must not imply or refer to any thyroid related diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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	700 mg
Equivalent: Brassica oleracea var. italica (Dry)	700 mg
selenomethionine	62.5 microgram
Equivalent: selenium	25 microgram

Other Ingredients (Excipients)

colloidal anhydrous silica
 disodium edetate
 gellan gum
 hypromellose
 magnesium stearate

Public Summary



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

microcrystalline cellulose

potable water

potassium acetate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary