



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	282577	GeneActiv Formulation D
ARTG entry for	Medicine Listed	
Sponsor	Cell-Logic Pty Ltd	
Postal Address	132-140 Ross Court, Cleveland, QLD, 4163 Australia	
ARTG Start Date	16/11/2016	
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 D

Product Type	Effective Date
Single Medicine Product	6/09/2019

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 liver cleansing/detoxification processes
- Helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Aid/assist healthy red blood cell production
- Helps enhance/promote red blood cell health
- Helps enhance/promote red blood cell health
- Maintain/support blood health
- 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
- Helps enhance/improve/promote immune system function
- Maintain/support healthy immune system function

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Maintain/support immune system to fight illness
 Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
 Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 Maintain/support (state vitamin/mineral/nutrient) levels in the body
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 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)
 Aids/assists the body to cope with environmental stress
 Maintain/support female reproductive system health
 Maintain/support reproductive system health in females
 Maintain/support reproductive system health
 Maintain/support reproductive system health in males
 Help maintain/support healthy prostate function
 Helps enhance/promote prostate health
 Maintain/support prostate health

Indication Requirements

Product presentation must not imply or refer to drugs/alcohol.
 Product presentation must not imply or refer to serious immunological diseases.
 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 serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.
 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.
 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.
 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 cardiovascular conditions.
 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.
 Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
 'Contains gluten (or words to that effect)'

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

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Biotin	10 microgram
borax	250 microgram
Equivalent: boron	28.35 microgram
Brassica oleracea var. italica sprout Powder	250 mg
Equivalent: Brassica oleracea var. italica (Dry)	250 mg
calcium ascorbate	7.5 mg
Equivalent: ascorbic acid	6.18 mg
Equivalent: calcium	705 microgram
calcium folinate	54.02 microgram
Equivalent: folic acid	50 microgram
calcium pantothenate	10.92 mg
Equivalent: pantothenic acid	10 mg
Equivalent: calcium	917 microgram
chromic chloride hexahydrate	515 microgram
Equivalent: chromium	100 microgram
colecalfiferol	.0062 mg
Cucumis melo fruit flesh Juice powder	831 microgram
Equivalent: Cucumis melo (Fresh)	831 mg
levomefolate calcium	54.2 microgram
Equivalent: levomefolic acid	50 microgram
Equivalent: calcium	4.2 microgram
manganese amino acid chelate	12.5 mg
Equivalent: manganese	1.25 mg
mecobalamin (co-methylcobalamin)	12.5 microgram
mixed (low-alpha type) tocopherols concentrate	3.9 mg
molybdenum trioxide	14.92 microgram
Equivalent: molybdenum	10 microgram
nicotinamide	10 mg
potassium iodide	32.7 microgram
Equivalent: iodine	25 microgram
Equivalent: potassium	7.7 microgram
pyridoxal 5-phosphate	2.92 mg
Equivalent: pyridoxine	2 mg
retinol acetate	37.95 microgram
riboflavin sodium phosphate	6.58 mg
Equivalent: riboflavin	5 mg
selenomethionine	15.625 microgram
Equivalent: selenium	6.25 microgram
thiamine hydrochloride	6.25 mg
Equivalent: thiamine	5.57 mg
zinc amino acid chelate	12.5 mg
Equivalent: zinc	2.5 mg

Other Ingredients (Excipients)

Acacia
butylated hydroxytoluene
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
disodium edetate
dl-alpha-tocopherol
Gelatin

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gellan gum
hypromellose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide
starch sodium octenyl succinate
sucrose
Triticum aestivum

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