



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	282577	GeneActiv Formulation D
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Cell-Logic Pty Ltd	
<b>Postal Address</b>	132-140 Ross Court, Cleveland, QLD, 4163 Australia	
<b>ARTG Start Date</b>	16/11/2016	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

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  
Maintain/support reproductive system health in males  
Maintain/support reproductive system health in females  
Help maintain/support healthy prostate function  
Helps enhance/promote prostate health  
Maintain/support prostate health

#### Indication Requirements

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 drugs/alcohol.  
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 any thyroid related diseases.  
Product presentation must not imply or refer to infertility.  
Product presentation must only refer to detoxification in relation to natural body processes.  
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 disease in any body organ, in particular the kidney or liver.  
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

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
-----------	-----------------

#### Components

##### 1 . Formulation 1

Dosage Form	Capsule, hard
-------------	---------------

Route of Administration	Oral
-------------------------	------

#### Visual Identification

#### Active Ingredients



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

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

**Other Ingredients (Excipients)**

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



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

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

© 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