Public Summary

Summary for ARTG Entry:	185234 EnduraCell PLUS
ARTG entry for	Medicine Listed
Sponsor	Cell-Logic Pty Ltd
Postal Address	ROSS COURT CENTRAL, 132-140, Cleveland, QLD, 4163 Australia
ARTG Start Date	15/06/2011
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 . EnduraCell PLUS

Product Type	Single Medicine Product	**Effective Date**	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

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

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

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.

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 immunological diseases.

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.

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

microcrystalline cellulose

potable water

potassium acetate

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