



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|--------------|
| Summary for ARTG Entry: | 329888 | Zinc Sustain |
| ARTG entry for | Medicine Listed | |
| Sponsor | FIT-BioCeuticals Limited | |
| Postal Address | Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia | |
| ARTG Start Date | 13/02/2020 | |
| 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.

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 . Zinc Sustain

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 25/09/2020 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support collagen formation
Maintain/support energy production
Maintain/support healthy eye function
Helps maintain/support eye retina health
Maintain/support healthy eyesight/vision
Maintain/support healthy growth and development
Helps maintain/support healthy blood sugar/glucose
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintains/support healthy foetal development
Maintain/support healthy reproductive hormones
Helps maintain/support testosterone formation/synthesis in males
Help maintain/support healthy prostate function
Maintain/support sperm health
Maintain/support skin health
Maintain/support wound healing

Indication Requirements



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Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to serious immunological diseases.

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 mental illnesses, disorders or conditions.

Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to hormone imbalances.

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 infertility.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Additional Product information

Pack Size/Poison information

| Pack Size | Poison Schedule |
|-----------|-----------------|
|-----------|-----------------|

Components

1 . Formulation 1

| | |
|--------------------------------|---------------------|
| Dosage Form | Tablet, film coated |
| Route of Administration | Oral |

Visual Identification

Active Ingredients

| | |
|-------------------------------------|--------------------|
| ascorbic acid | 100.0065 mg |
| magnesium amino acid chelate | 100 mg |
| Equivalent: magnesium | 20 mg |
| pyridoxine hydrochloride | 30 mg |
| Equivalent: pyridoxine | 24.75 mg |
| retinol acetate | .5175 mg |
| zinc amino acid chelate | 150 mg |
| Equivalent: zinc | 30 mg |

Other Ingredients (Excipients)

- butylated hydroxytoluene
- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- Gelatin
- hypromellose

Public Summary



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iron oxide black
iron oxide red
iron oxide yellow
macrogol 400
magnesium stearate
maize starch
microcrystalline cellulose
silicon dioxide
sucrose
titanium dioxide

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