



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|--------------|
| Summary for ARTG Entry: | 330859 | S.F.M. Xcell |
| ARTG entry for | Medicine Listed | |
| Sponsor | Bio Concepts Pty Ltd | |
| Postal Address | PO Box 190, Banyo, Brisbane, QLD, 4014 Australia | |
| ARTG Start Date | 5/03/2020 | |
| 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.

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 . S.F.M. Xcell

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 13/10/2021 |
|---------------------|-------------------------|-----------------------|------------|

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
- Maintain/support energy levels
- Maintain/support body metabolism/metabolic rate
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support healthy growth and development
- Traditionally used in Ayurvedic medicine to restorative tonic
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production

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Maintain/support smell sensation
Maintain/support taste sensation
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps decrease/reduce homocysteine levels
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps maintain/support cellular uptake of (state vitamin/mineral/nutrient)
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
Traditionally used in Ayurvedic medicine to aids/assists the body to cope with environmental stress
Traditionally used in Ayurvedic medicine to support healthy body stress recovery
Support healthy stress response in the body
Traditionally used in Ayurvedic medicine to support healthy stress response in the body
Maintain/support cognitive development
Traditionally used in Ayurvedic medicine to nerve tonic
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Traditionally used in Ayurvedic medicine to nervine/support nervous system
Maintain/support brain/central nervous system development
Maintain/support nervous system function
Maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones
Maintain/support sperm production
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing
Maintain/support skin repair/healing/regeneration

Indication Requirements

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

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

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

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.

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.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to neurological conditions or developmental delays.

Product presentation must not imply or refer to infertility.

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

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Product presentation must not imply or refer to chronic fatigue syndrome.

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 hormone imbalances.

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
 If symptoms persist consult your healthcare practitioner (or words to that effect).
 Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
 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 Tablet, film coated
Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|---|------------------------|
| calcium folinate | 270.1 microgram |
| Equivalent: folic acid | 250 microgram |
| calcium pantothenate | 30 mg |
| Equivalent: calcium | 2.52 mg |
| Equivalent: pantothenic acid | 27.48 mg |
| chromium nicotinate | 120 microgram |
| Equivalent: chromium | 15 microgram |
| hydroxocobalamin | 500 microgram |
| inositol | 300 mg |
| nicotinamide | 30 mg |
| nicotinic acid | 5 mg |
| potassium iodide | 130.8 microgram |
| Equivalent: iodine | 100 microgram |
| pyridoxal 5-phosphate monohydrate | 23.5 mg |
| Equivalent: pyridoxine | 15 mg |
| Rehmannia glutinosa root Extract dry concentrate | 40 mg |
| Equivalent: Rehmannia glutinosa (Dry) | 400 mg |
| riboflavin sodium phosphate | 13.33 mg |
| Equivalent: riboflavin | 10 mg |
| selenomethionine | 187.5 microgram |
| Equivalent: selenium | 75 microgram |
| thiamine hydrochloride | 11.21 mg |
| Equivalent: thiamine | 10 mg |
| tyrosine | 500 mg |
| Withania somnifera root Extract dry concentrate | 24 mg |
| Equivalent: Withania somnifera (Dry) | 300 mg |
| zinc citrate dihydrate | 30.77 mg |
| Equivalent: zinc | 10 mg |

Other Ingredients (Excipients)



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calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

crospovidone

hypromellose

macrogol 400

magnesium stearate

microcrystalline cellulose

povidone

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