



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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
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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 only refer to detoxification in relation to natural body processes.

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

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 cardiovascular conditions.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

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 neurological conditions or developmental delays.

Product presentation must not imply or refer to infertility.

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

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.

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.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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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