Public Summary

Summary for ARTG Entry:	345117 BioCell Protect
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	30/09/2020
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 . BioCell Protect

Product Type Single Medicine Product **Effective Date** 8/10/2021

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support healthy immune system function

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Indication Requirements

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 immunological diseases.

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.

The recommended dose of this medicine provides small amounts of caffeine

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

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Visual Identification

Active Ingredients	
alpha lipoic acid	**4 mg**
Brassica oleracea var. italica sprout Extract dry concentrate	**125 microgram**
Equivalent: Brassica oleracea var. italica (Dry)	37.5 mg
Camellia sinensis leaf Extract dry concentrate standardised	**125 mg**
Equivalent: Camellia sinensis (Dry)	3.75 g
curcumin	**5 mg**
quercetin dihydrate	**125 mg**
Reynoutria japonica root Extract dry concentrate standardised	**100 mg**
Equivalent: Reynoutria japonica (Dry)	10 g
selenomethionine	**18.63 microgram**
Equivalent: selenium	7.5 microgram
zinc amino acid chelate	**18.75 mg**
Equivalent: zinc	3.75 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
citric acid
colloidal anhydrous silica
croscarmellose sodium
crospovidone
ethylcellulose
Ghatti Gum
hypromellose
macrogol 8000
magnesium stearate
maltodextrin
maltose
microcrystalline cellulose

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