Public Summary

Summary for ARTG Entry:	119956	BLACKMORES PROFESSIONAL BIO CHROMIUM PLUS

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	20/06/2005
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 . BLACKMORES PROFESSIONAL BIO CHROMIUM PLUS

Product Type	Single Medicine Product	**Effective Date**	20/12/2019

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps convert (state food) into energy

Helps maintain/support healthy blood sugar/glucose

Aid/assist digestion/breakdown of dietary fat

Aid/assist/helps glucose/sugar/carbohydrate metabolism

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

Maintain/support nervous system function

Indication Requirements

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.

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

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.

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 pantothenate	**25 mg**
Equivalent: pantothenic acid	22.9 mg
chromic chloride hexahydrate	**768 microgram**
Equivalent: chromium	150 microgram
chromium picolinate	**402 microgram**
Equivalent: chromium	50 microgram
cyanocobalamin	**300 microgram**
dibasic potassium phosphate	**33 mg**
Equivalent: potassium	14.8 mg
folic acid	**150 microgram**
magnesium phosphate pentahydrate	**65 mg**
Equivalent: magnesium	13.4 mg
manganese amino acid chelate	**20 mg**
Equivalent: manganese	2 mg
nicotinamide	**50 mg**
pyridoxine hydrochloride	**25 mg**
Equivalent: pyridoxine	20.57 mg
zinc amino acid chelate	**25 mg**
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
calcium phosphate
Carnauba Wax
colloidal anhydrous silica
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
purified talc
sodium starch glycollate
tapioca starch

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