



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	221460	CARDIOX BANANA BERRY FLAVOUR METAGENICS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	19/03/2014	
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 . CARDIOX BANANA BERRY FLAVOUR METAGENICS

Product Type	Single Medicine Product	Effective Date	1/05/2020
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

Maintain/support general health and wellbeing
Maintain/support blood health
Maintain/support cardiovascular system health
Maintain/support heart health
Helps decrease/reduce homocysteine levels
Support healthy stress response in the body in athletes
Support healthy stress response in the body when dietary intake is inadequate

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This product 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.

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. If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

calcium amino acid chelate	38.96 mg/g
Equivalent: calcium	7.79 mg/g
calcium folinate	21.04 microgram/g
Equivalent: folic acid	19.48 microgram/g
chromic chloride hexahydrate	66.62 microgram/g
Equivalent: chromium	12.99 microgram/g
cyanocobalamin	.0259 mg/g
magnesium amino acid chelate	389.6 mg/g
Equivalent: magnesium	38.96 mg/g
pyridoxal 5-phosphate	3.25 mg/g
Equivalent: pyridoxine	2.22 mg/g
riboflavin sodium phosphate	324.68 microgram/g
selenomethionine	16.23 microgram/g
Equivalent: selenium	6.49 microgram/g
taurine	389.6 mg/g

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
Flavour
polacrillin
potable water
Steviol glycosides

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary