



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	320522	METAGENICS RESIST-X
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	22/07/2019	
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 . METAGENICS RESIST-X

Product Type	Single Medicine Product	Effective Date	11/02/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support energy production
- Helps maintain/support healthy blood sugar/glucose
- Traditionally used in Ayurvedic medicine to maintain/support healthy pancreatic function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Help maintain/support emotional wellbeing
- Help maintain/support emotional wellbeing in females
- Aid/assist/helps synthesis of neurotransmitters

Indication Requirements

- 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).
- 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 any pancreas related diseases.

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.
 WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.

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[Contains vitamin B6].

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

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

Adults only.

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg 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

Visual Identification

Active Ingredients

Biotin	4 mg
chromic chloride hexahydrate	1.41 mg
Equivalent: chromium	275 microgram
chromium picolinate	201.13 microgram
Equivalent: chromium	25 microgram
Cinnamomum cassia stem bark Extract dry concentrate	250 mg
Gymnema sylvestre leaf Extract dry concentrate standardised	50 mg
Equivalent: Gymnema sylvestre (Dry)	2 g
nicotinamide	50 mg
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.13 mg
Theobroma cacao seed Extract dry concentrate standardised	555.56 mg
Equivalent: Theobroma cacao (Dry)	2.5 g
zinc amino acid chelate	100 mg
Equivalent: zinc	20 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
 Carnauba Wax
 citric acid
 colloidal anhydrous silica
 crospovidone
 glyceryl monostearate
 hypromellose
 macrogol 400
 magnesium stearate
 microcrystalline cellulose
 povidone

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