



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	371331	METAGENICS ALERGENICS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	20/07/2021	
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 ALERGENICS

Product Type	Single Medicine Product	Effective Date	10/02/2023
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Permitted Indications

Maintain/support natural liver cleansing/detoxification processes
Traditionally used in Chinese medicine to relieve eye redness
Traditionally used in Chinese medicine to relieve eye soreness
Maintain/support healthy mucous linings of the digestive system
Maintain/support gastrointestinal system health
Maintain/support gastrointestinal mucosal membrane health
Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of mild allergies
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of allergic rhinitis
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of allergic rhinitis in children
Traditionally used in Chinese medicine to maintain/support immune system health
Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function
Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function in children
Traditionally used in Chinese medicine to maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function

Indication Requirements

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to drugs/alcohol.
Product presentation must only refer to detoxification in relation to natural body processes.
Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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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. If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

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

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

choline bitartrate	208.33 mg/g
colecalfiferol	1.7361 microgram/g
Ganoderma lucidum fruiting body Extract dry concentrate	49.02 mg/g
Equivalent: Ganoderma lucidum (Dry)	833.33 mg/g
glutamine	486.11 mg/g
Lentinula edodes fruiting body Extract dry concentrate	52.08 mg/g
Equivalent: Lentinula edodes (Dry)	833.33 mg/g
Perilla frutescens leaf Extract dry concentrate	28.94 mg/g
Equivalent: Perilla frutescens (Dry)	347.22 mg/g
retinol palmitate	.1932 mg/g
Equivalent: vitamin A	.1042 mg/g
Scutellaria baicalensis root Extract dry concentrate	41.67 mg/g
Equivalent: Scutellaria baicalensis (Dry)	416.7 mg/g
Silybum marianum seed Extract dry concentrate	11.9 mg/g
Equivalent: Silybum marianum (Dry)	833.33 mg/g
zinc amino acid chelate	4.17 mg/g
Equivalent: zinc	833.33 microgram/g

Other Ingredients (Excipients)

Acacia
citric acid
dl-alpha-tocopherol
Flavour
Gelatin
maize starch
medium chain triglycerides
polydextrose
silicon dioxide
Steviol glycosides
sucrose

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