



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	294466	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	29/09/2017	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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	4/12/2020
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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
- 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 maintain/support immune system health
- Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function
- Maintain/support healthy immune system function
- Maintain/support healthy gastrointestinal immune function

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- 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.



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

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

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 Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

choline bitartrate	208.33 mg/g
colecalfiferol	1.735 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	190.85 microgram/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 microgram/g

Other Ingredients (Excipients)

Acacia

aluminium sodium silicate

aluminium starch octenylsuccinate

butylated hydroxytoluene

dl-alpha-tocopherol

Flavour

Gelatin

maize starch

medium chain triglycerides

polydextrose

potable water

silicon dioxide

Steviol glycosides

sucrose

Public Summary

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