



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	349170	METAGENICS GLUTAGENICS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	20/11/2020	
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 GLUTAGENICS

Product Type	Single Medicine Product	Effective Date	20/11/2020
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Permitted Indications

Maintain/support energy production
Maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
Maintain/support healthy digestion
Maintain/support healthy mucous linings of the digestive system
Traditionally used in Ayurvedic medicine to maintain/support gastrointestinal system health
Maintain/support gastrointestinal system health
Maintain/support gastrointestinal mucosal membrane health
Aids/assists repair of gastrointestinal/gut wall lining
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Ayurvedic medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation
Traditionally used in Western herbal medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve gastrointestinal pain
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve digestive spasms
Maintain/support healthy gastrointestinal immune function
Traditionally used in Ayurvedic medicine to antispasmodic/spasmolytic

Indication Requirements

Product presentation must not imply or refer to gastro oesophageal reflux disease.
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.
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 serious musculoskeletal or neurological conditions.

Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

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

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).

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

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

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.

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

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Aloe vera leaf inner juice Dry	3.25 mg/g
Equivalent: Aloe vera (Fresh)	649.35 mg/g
Boswellia serrata gum oleoresin Extract dry concentrate	19.48 mg/g
Equivalent: Boswellia serrata (Fresh)	194.8 mg/g
colecalfiferol	1.6233 microgram/g
glutamine	285.71 mg/g
Larix arabinogalactan	259.74 mg/g
retinol palmitate	.1805 mg/g
zinc amino acid chelate	9.74 mg/g
Equivalent: zinc	1.95 mg/g

Other Ingredients (Excipients)

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

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