



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	382592	METAGENICS GUT INFLAMX
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	14/01/2022	
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 GUT INFLAMX

Product Type	Single Medicine Product	Effective Date	14/01/2022
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Maintain/support general health and wellbeing
Anti-inflammatory/relieve inflammation
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve bowel discomfort
Maintain/support healthy mucous linings of the digestive system
Maintain/support digestive system health
Traditionally used in Ayurvedic medicine to maintain/support gastrointestinal system health
Maintain/support gastrointestinal system health
Maintain/support gastrointestinal mucosal membrane health
Traditionally used in Ayurvedic medicine to relieve digestive discomfort
Traditionally used in Ayurvedic medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve gastrointestinal pain
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function
Maintain/support nervous system health
Maintain/support nervous system function

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



Australian Government
Department of Health
Therapeutic Goods Administration

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.

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (or words to that effect).

Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical advice (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Andrographis paniculata herb top Extract dry concentrate	160 mg
Equivalent: Andrographis paniculata (Dry)	2.56 g
Boswellia serrata gum oleoresin Extract dry concentrate	75 mg
Equivalent: Boswellia serrata (Dry)	750 mg
colecalfiferol	6.25 microgram
coptis chinensis rhizome Extract dry concentrate	166.67 mg
Equivalent: coptis chinensis (Dry)	1.67 g
polaprezinc	28.09 mg
Equivalent: zinc	6.25 mg
Zingiber officinale rhizome Extract dry concentrate	17.81 mg
Equivalent: Zingiber officinale (Dry)	747.94 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
calcium hydroxide
disodium edetate
dl-alpha-tocopherol
gellan gum
hypromellose
magnesium stearate
maize starch
medium chain triglycerides
potable water
potassium acetate
silicon dioxide
sucrose

Public Summary

© 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>.