Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370563	Gluten Relieve
ARTG entry for	Medicine Listed	
Sponsor	Miasca Investments Pty Ltd	
Postal Address	PO Box 1786, Noosaville BC, QLD, 4566 Australia	
ARTG Start Date	5/07/2021	
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 . Gluten Relieve

Product Type Single Medicine Product **Effective Date** 5/07/2021

Permitted Indications

Decrease/reduce/relieve colic (wind/gas pain)

Decrease/reduce/relieve excess intestinal gas

Maintain/support healthy digestive system function

Maintain/support healthy digestion

Maintain/support digestion/assimilation of nutrients

Aid/assist digestion/breakdown of dietary fat

Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid

Aid/assist digestion of glucose/sugar/carbohydrates

Helps reduce occurrence of symptoms of medically diagnosed gluten sensitivity caused by inadvertent gluten ingestion

Maintain/support digestive system health

Decrease/reduce/relieve abdominal bloating/distention

Decrease/reduce/relieve abdominal cramping

Decrease/reduce/relieve abdominal feeling of fullness

Relieve digestive discomfort

Helps decrease/reduce/relieve symptoms of food intolerance

Helps reduce occurrence of symptoms of food intolerance

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.

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

Product presentation must not imply or refer to individuals with coeliac disease or dermatitis herpetiformis.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Label statement: For use only in conjunction with a gluten-free diet.

Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

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).

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

Amylase	**10 thousand DU**
cellulase	**4 thousand CU**
lipase	**40 LipU**
protease	**31.25 Thousand HUT**

Other Ingredients (Excipients)

hypromellose
medium chain triglycerides
microcrystalline cellulose
purified water

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