



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	351742	Gluteneze
ARTG entry for	Medicine Listed	
Sponsor	Miasca Investments Pty Ltd	
Postal Address	PO Box 1786, Noosaville BC, QLD, 4566 Australia	
ARTG Start Date	15/12/2020	
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 . Gluteneze

Product Type	Single Medicine Product	Effective Date	15/06/2021
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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 reduce occurrence of symptoms of food intolerance

Indication Requirements

- Product presentation must not imply or refer to individuals with coeliac disease or dermatitis herpetiformis.
- Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.
- 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.
- 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.
- Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
- Label statement: For use only in conjunction with a gluten-free diet.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.

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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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