



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	370563	Gluten Relieve
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Miasca Investments Pty Ltd	
<b>Postal Address</b>	PO Box 1786, Noosaville BC, QLD, 4566 Australia	
<b>ARTG Start Date</b>	5/07/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/07/2021
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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 decrease/reduce/relieve symptoms of food intolerance  
Helps reduce occurrence of symptoms of food intolerance

#### 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.  
Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.  
Label statement: For use only in conjunction with a gluten-free diet.  
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.  
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 or raising blood sugar/glucose levels from outside of the normal healthy range.



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

**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**

<b>Amylase</b>	<b>10 thousand DU</b>
<b>cellulase</b>	<b>4 thousand CU</b>
<b>lipase</b>	<b>40 LipU</b>
<b>protease</b>	<b>31.25 Thousand HUT</b>

**Other Ingredients (Excipients)**

hypromellose  
medium chain triglycerides  
microcrystalline cellulose  
purified water

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