



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

## Public Summary

<b>Summary for ARTG Entry:</b>	343748	MultiGest Enzymes
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	18/09/2020	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . MultiGest Enzymes

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	18/09/2020
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### Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to helps enhance/promote healthy digestive system function
- Aid/assist digestion of lactose
- Aid/assist/helps digestion of (state nutrient)
- Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to relieve digestive discomfort

### Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- Product presentation must not imply or refer to eating disorders.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

- Use in children under 12 years is not recommended.
- Do not use if pregnant or likely to become pregnant (or words to that effect)
- Do not use while breastfeeding.



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**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>12 thousand DU</b>
<b>bromelains</b>	<b>40 mg</b>
<b>cellulase</b>	<b>1000 CU</b>
<b>Foeniculum vulgare seed Extract dry concentrate</b>	<b>167 mg</b>
Equivalent: Foeniculum vulgare (Dry)	1.67 g
<b>Gentiana lutea root Extract dry concentrate</b>	<b>134 mg</b>
Equivalent: Gentiana lutea (Dry)	670 mg
<b>lipase</b>	<b>500 LipU</b>
<b>protease</b>	<b>30 Thousand HUT</b>
<b>tilactase</b>	<b>1.5 thousand ALU</b>

**Other Ingredients (Excipients)**

**disodium edetate**  
**gellan gum**  
**hypromellose**  
**potable water**  
**potassium acetate**  
**Rice bran**

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