# Public Summary

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| **Summary for ARTG Entry:** | 353138 METAGENICS VEGETARIAN DIGESTIVE ENZYMES |
| **ARTG entry for** | Medicine Listed |
| **Sponsor** | Metagenics (Aust) Pty Ltd |
| **Postal Address** | PO Box 675, VIRGINIA BC, QLD, 4014<br>Australia |
| **ARTG Start Date** | 15/01/2021 |
| **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 . METAGENICS VEGETARIAN DIGESTIVE ENZYMES

**Product Type** Single Medicine Product **Effective Date** 19/04/2021

**Permitted Indications**

Maintain/support healthy digestion

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

Aid/assist digestion of glucose/sugar/carbohydrates

Aid/assist/helps digestion of (state nutrient)

**Indication Requirements**

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.

**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**

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| **Dosage Form** | Capsule, hard |
| **Route of Administration** | Oral |
| **Visual Identification** | |

**Active Ingredients**

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| **Amylase** | **15 thousand DU** |
| **cellulase** | **2 thousand CU** |
| **lipase** | **600 LipU** |
| **protease** | **30 Thousand HUT** |

**Other Ingredients (Excipients)**

**calcium hydrogen phosphate dihydrate**
**colloidal anhydrous silica**
**disodium edetate**
**gellan gum**
**hypromellose**
**magnesium stearate**
**maltodextrin**
**microcrystalline cellulose**
**potable water**
**potassium acetate**



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