# Public Summary

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| **Summary for ARTG Entry:** | 311209 GI Revive |
| **ARTG entry for** | Medicine Listed |
| **Sponsor** | Designs For Health Pty Ltd |
| **Postal Address** | 1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia |
| **ARTG Start Date** | 6/11/2018 |
| **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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . GI Revive

**Product Type** Single Medicine Product **Effective Date** 21/01/2020

#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support gastrointestinal system health

Helps decrease/reduce/relieve mild gastrointestinal tract inflammation

Maintain/support healthy immune system function

Maintain/support wound healing

#### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious immunological diseases.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### Additional Product information

**Pack Size/Poison information**

| Pack Size | Poison Schedule |
|---|---|

**Components**

**1 . Formulation 1**

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| **Dosage Form** | Powder, oral |
| **Route of Administration** | Oral |
| **Visual Identification** | |

**Active Ingredients**

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| **Aloe vera leaf Extract dry concentrate** | **312.5 microgram/g** |
| Equivalent: Aloe vera (Dry) | 62.5 mg/g |
| **Althaea officinalis root Extract dry concentrate** | **625 microgram/g** |
| Equivalent: Althaea officinalis (Dry) | 12.5 mg/g |
| **dimethyl sulfone** | **12.5 mg/g** |
| **glutamine** | **250 mg/g** |
| **Glycyrrhiza glabra root Extract dry concentrate** | **6.25 mg/g** |
| Equivalent: Glycyrrhiza glabra (Dry) | 50 mg/g |
| **Hibiscus esculentus fruit Extract dry concentrate** | **3.13 mg/g** |
| Equivalent: Hibiscus esculentus (Dry) | 12.5 mg/g |
| **Matricaria chamomilla flower Extract dry concentrate** | **2.5 mg/g** |
| Equivalent: Matricaria chamomilla (Dry) | 12.5 mg/g |
| **pectin** | **125 mg/g** |
| **polaprezinc** | **9.38 mg/g** |
| Equivalent: zinc | 2 mg/g |
| **quercetin** | **12.5 mg/g** |
| **Ulmus rubra stem bark inner Extract dry concentrate** | **15.63 mg/g** |
| Equivalent: Ulmus rubra (Dry) | 62.5 mg/g |
| **Uncaria tomentosa root Extract dry concentrate** | **25 mg/g** |
| Equivalent: Uncaria tomentosa (Dry) | 125 mg/g |

**Other Ingredients (Excipients)**

**calcium hydrogen phosphate dihydrate**
**citric acid**
**colloidal anhydrous silica**
**Flavour**
**maltodextrin**
**silicon dioxide**
**Steviol glycosides**

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