



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	377524	GI Revive
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Designs For Health Pty Ltd	
<b>Postal Address</b>	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
<b>ARTG Start Date</b>	5/11/2021	
<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 . GI Revive

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/11/2022
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Maintain/support general health and wellbeing  
Maintain/support healthy mucous linings of the digestive system  
Maintain/support gastrointestinal system health  
Helps decrease/reduce/relieve mild gastrointestinal tract inflammation  
Traditionally used in Western herbal medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation  
Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes  
Maintain/support immune system health  
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

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Aloe vera leaf Juice powder</b>	<b>312.5 microgram/g</b>
Equivalent: Aloe vera (Juice fresh)	62.5 mg/g
<b>Althaea officinalis root Extract dry concentrate</b>	<b>625 microgram/g</b>
Equivalent: Althaea officinalis (Dry)	12.5 mg/g
<b>dimethyl sulfone</b>	<b>12.5 mg/g</b>
<b>glutamine</b>	<b>250 mg/g</b>
<b>Glycyrrhiza glabra root Extract dry concentrate</b>	<b>6.25 mg/g</b>
Equivalent: Glycyrrhiza glabra (Dry)	50 mg/g
<b>Hibiscus esculentus fruit Extract dry concentrate</b>	<b>3.125 mg/g</b>
Equivalent: Hibiscus esculentus (Dry)	12.5 mg/g
<b>Matricaria chamomilla flower Extract dry concentrate</b>	<b>2.5 mg/g</b>
Equivalent: Matricaria chamomilla (Dry)	12.5 mg/g
<b>pectin</b>	<b>125 mg/g</b>
<b>polaprezinc</b>	<b>9.302 mg/g</b>
Equivalent: zinc	2 mg/g
<b>quercetin dihydrate</b>	<b>12.5 mg/g</b>
<b>Ulmus rubra stem bark inner Extract dry concentrate</b>	<b>15.625 mg/g</b>
Equivalent: Ulmus rubra (Dry)	62.5 mg/g
<b>Uncaria tomentosa root Extract dry concentrate</b>	<b>25 mg/g</b>
Equivalent: Uncaria tomentosa (Dry)	125 mg/g

**Other Ingredients (Excipients)**

**citric acid**

**colloidal anhydrous silica**

**Flavour**

**maltodextrin**

**Stevia rebaudiana**

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