

### **Australian Government**

## **Department of Health and Aged Care**

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 335339 GastroMend-HP

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 28/04/2020
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 . GastroMend-HP

Product Type Single Medicine Product Effective Date 8/04/2025

### **Permitted Indications**

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support collagen formation

Maintain/support general health and wellbeing

Maintain/support connective tissue health

Aid/assist/helps connective tissue production/formation

Traditionally used in Western herbal medicine to maintain/support gastrointestinal system health

Traditionally used in Western herbal medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Helps stimulate a healthy immune system response

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Maintain/support wound healing

# Indication Requirements

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

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

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

#### Standard Indications

No Standard Indications included on Record

#### **Specific Indications**

No Specific Indications included on Record

## Warnings

For practitioner dispensing only.

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## This is not an ARTG Certificate document.



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### **Additional Product information**

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Pack Size **Poison Schedule** 

#### Components

#### 1 . Formulation 1

Capsule, hard **Dosage Form** 

**Route of Administration** 

Oral

Visual Identification

**Active Ingredients** 

ascorbic acid 125 mg Glycyrrhiza glabra root Extract dry concentrate 46.88 mg Equivalent: Glycyrrhiza glabra (Dry) 375.04 mg Mastic 250 mg polaprezinc 18.78 mg Equivalent: zinc 4 mg

### Other Ingredients (Excipients)

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

purified water silicon dioxide

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