



Australian Government
Department of Health
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	9/03/2022
---------------------	-------------------------	-----------------------	-----------

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

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious immunological diseases.
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

No Warnings included on Record

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary