



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	395210	GI Microb-X
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	31/08/2022	
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 . GI Microb-X

Product Type	Single Medicine Product	Effective Date	31/08/2022
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Traditionally used in Western herbal medicine to vermifuge/helps remove intestinal threadworms/pinworms

Traditionally used in Chinese medicine to vermifuge/helps remove intestinal threadworms/pinworms

Maintain/support gastrointestinal system health

Indication Requirements

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

Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not recommended for use by pregnant and lactating women (or words to that effect).

If symptoms persist consult your healthcare practitioner (or words to that effect).

Do not use if pregnant or likely to become pregnant (or words to that effect)

Additional Product information

Pack Size/Poison information

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

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Visual Identification

Active Ingredients

Artemisia annua herb Extract dry concentrate	75 mg
Equivalent: Artemisia annua (Dry)	750 mg
Berberis aristata root Extract dry concentrate	50 mg
Equivalent: Berberis aristata (Dry)	2 g
Berberis vulgaris root Extract dry concentrate	25 mg
Equivalent: Berberis vulgaris (Dry)	275 mg
Juglans nigra fruit hull Extract dry concentrate	75 mg
Equivalent: Juglans nigra (Dry)	375 mg
Punica granatum fruit hull Extract dry concentrate	100 mg
Equivalent: Punica granatum (Dry)	1.5 g
Punica granatum fruit Extract dry concentrate	50 mg
Equivalent: Punica granatum (Dry)	750 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
medium chain triglycerides
microcrystalline cellulose
purified water

© 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