Public Summary

Summary for ARTG Entry:	336384 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	14/05/2020
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

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.

The warning statement 'Do not use if pregnant or likely to become pregnant' must be displayed on the medicine label.

Products

1 . GI Microb-X

Product Type Single Medicine Product **Effective Date** 14/05/2020

Permitted Indications

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

Indication Requirements

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

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

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).

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

Artemisia annua herb Extract dry concentrate standardised	**75 mg**
Equivalent: Artemisia annua (Dry)	1.5 g
Berberis aristata root Extract dry concentrate	**100 mg**

Equivalent: Berberis aristata (Dry)	4 g
Berberis vulgaris root Extract dry concentrate standardised	**50 mg**
Equivalent: Berberis vulgaris (Dry)	550 mg
Juglans nigra fruit hull Extract dry concentrate	**100 mg**
Equivalent: Juglans nigra (Dry)	1000 mg
Tribulus terrestris root Extract dry concentrate	**200 mg**
Equivalent: Tribulus terrestris (Dry)	10 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
medium chain triglycerides
purified water

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