Public Summary

Summary for ARTG Entry:	308293 ZymeGest
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	16/08/2018
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . ZymeGest

Product Type	Single Medicine Product	**Effective Date**	26/06/2020

Permitted Indications

Maintain/support healthy digestive system function

Maintain/support healthy digestion

Aid/assist digestion/breakdown of dietary fat

Aid/assist digestion of lactose

Decrease/reduce/relieve symptoms of lactose intolerance

Indication Requirements

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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

No Warnings included on Record

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

Amylase	**12 thousand DU**
cellulase	**1 thousand CU**
lipase	**500 LipU**
protease	**30 Thousand HUT**
tilactase	**1.5 thousand ALU**

Other Ingredients (Excipients)

betaine hydrochloride
calcium hydrogen phosphate
colloidal anhydrous silica
dextrin
disodium edetate
gellan gum
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
potable water
potassium acetate

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