



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	377414	Intolergest
ARTG entry for	Medicine Listed	
Sponsor	Thera Health Pty Ltd	
Postal Address	18/93 Rivergate Place, Murarrie, QLD, 4172 Australia	
ARTG Start Date	3/11/2021	
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 . Intolergest

Product Type	Single Medicine Product	Effective Date	3/11/2021
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Permitted Indications

- Maintain/support general health and wellbeing
- Helps stimulate/increase digestive enzymes
- Maintain/support healthy digestion
- Aid/assist digestion/breakdown of dietary fat
- Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid
- Aid/assist digestion of glucose/sugar/carbohydrates
- Aid/assist digestion of lactose
- Decrease/reduce/relieve symptoms of lactose intolerance

Indication Requirements

- Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
- Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
- 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
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Components

1 . Formulation 1

Dosage Form Capsule, hard
Route of Administration Oral

Visual Identification

Active Ingredients

Amylase	3.5 thousand DU
cellulase	350 CU
lipase	250 LipU
protease	24.5 Thousand HUT
tilactase	2.25 thousand ALU

Other Ingredients (Excipients)

hypromellose
maltodextrin
medium chain triglycerides
microcrystalline cellulose

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