



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	387759	Debloat and Digest+
ARTG entry for	Medicine Listed	
Sponsor	Ora Health Pty Ltd	
Postal Address	24/10-18 Orchard Road, Brookvale, NSW, 2100 Australia	
ARTG Start Date	2/05/2022	
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.

Products

1 . Debloat and Digest+

Product Type	Single Medicine Product	Effective Date	2/05/2022
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Permitted Indications

- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Maintain/support healthy digestive system function
- Maintain/support healthy digestion
- Aid/assist digestion/breakdown of dietary fat
- Aid/assist digestion of glucose/sugar/carbohydrates
- Aid/assist/helps digestion of (state nutrient)
- Maintain/support digestive system health
- Helps reduce occurrence of symptoms of indigestion/dyspepsia
- Decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Helps reduce occurrence of abdominal bloating
- Decrease/reduce/relieve abdominal feeling of fullness
- Decrease/reduce/relieve abdominal pain/discomfort
- Relieve excessive belching
- Decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Decrease/reduce/relieve symptoms of heartburn

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- 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.

Standard Indications

No Standard Indications included on Record

Specific Indications



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No Specific Indications included on Record

Warnings

Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.

Do not use while breastfeeding.

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

Use in children under 12 years is not recommended.

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

Visual Identification

Active Ingredients

Amylase	1.5 thousand DU
bromelains	.45 million PU
cellulase	150 CU
Foeniculum vulgare seed Extract dry concentrate	100 mg
Equivalent: Foeniculum vulgare (Dry)	1000 mg
Glycyrrhiza glabra root Extract dry concentrate standardised	75 mg
Equivalent: Glycyrrhiza glabra (Dry)	2062.5 mg
lipase	100 LipU
papain	8 mg
protease	1.8 Thousand HUT

Other Ingredients (Excipients)

colloidal anhydrous silica
dextrin
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water
sodium metabisulfite

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