

Australian Government

Department of Health

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 Australia	d Road, Brookvale, NSW, 2100		
ARTG Start Date	2/05/2022			
Product Category	Medicine			
Status	Active			
Approval Area	Listed Medicines			
Products				
1. Debloat and Digest+				

bloat and Digest

Product Type Single Medicine Product Effective Date

2/05/2022

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.

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.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Use in children under 12 years is not recommended.

Do not use while breastfeeding.

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.

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

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Additional Product information

Pack Size Poison Schedule Components 1. Formulation 1 Dosage Form Capsule, hard Route of Administration Oral Visual Identification Oral Active Ingredients 1.5 thous Amylase 1.5 thous bromelains .45 millio cellulase 150 CU Foeniculum vulgare seed Extract dry concentrate 100 mg Equivalent: Foeniculum vulgare (Dry) 1000 mg Equivalent: Glycyrrhiza glabra root Extract dry concentrate standardised 75 mg Equivalent: Glycyrrhiza glabra (Dry) 2062.5 m Iipase 100 LipU papain 8 mg protease 1.8 Thou dextrin hypromellose magnesium stearate	
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