



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		407669	EnteroMend
ARTG entry for	Medicine Listed		
Sponsor	Bio-Practica Pty Ltd		
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia		
ARTG Start Date	14/04/2023		
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 . EnteroMend

Product Type	Single Medicine Product	Effective Date	14/04/2023
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps enhance/promote collagen formation in females
Maintain/support collagen formation in females
Maintain/support collagen health in females
Maintain/support energy production
Helps maintain/support healthy acid/alkali balance in the body
Maintain/support general health and wellbeing
Demulcent/soothe irritated tissues
Maintain/support healthy digestive system function
Maintain/support healthy mucous linings of the digestive system
Maintain/support digestive system health
Maintain/support intestinal good/beneficial/friendly flora
Nourish good/beneficial/friendly intestinal flora
Maintain/support gastrointestinal system health
Maintain/support healthy gastrointestinal function
Maintain/support gastrointestinal mucosal membrane health
Maintain/support gastrointestinal mucosal membrane health
Soothe gastro-intestinal tract mucous membranes
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral) within normal range
Helps enhance/promote skin health in females
Maintain/support skin health



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Maintain/support skin health in females
Helps enhance/improve/promote/increase skin hydration in females
Maintain/support skin hydration in females
Maintain/support skin elasticity in females
Helps enhance/improve skin elasticity in females
Maintain/support skin integrity/structure
Maintain/support skin integrity/structure in females
Maintain/support skin regeneration
Maintain/support wound healing

Indication Requirements

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

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 serious immunological diseases.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The dose of fibre should be increased gradually. Fluid intake should be increased with an increasing dose of fibre.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Aloe vera leaf inner Juice powder	4.17 mg/g
Equivalent: Aloe vera (Juice fresh)	833.33 mg/g
glutamine	250 mg/g
guar galactomannan	416.67 mg/g
hydrolysed collagen	208.33 mg/g
zinc gluconate	8.15 mg/g
Equivalent: zinc	1.17 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica

Flavour

glycine

Stevia rebaudiana