



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	339054	Eagle Tresos Clinical Probiotic
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	7/07/2020	
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 . Eagle Tresos Clinical Probiotic

Product Type	Single Medicine Product	Effective Date	26/11/2020
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Permitted Indications

Maintain/support general health and wellbeing in adults
Maintain/support general health and wellbeing in children over 5 years of age
Maintain/support general health and wellbeing in adolescents
Maintain/support intestinal good/beneficial/friendly flora in adults
Maintain/support intestinal good/beneficial/friendly flora in adolescents
Maintain/support small intestine good/beneficial/friendly flora in adolescents
Maintain/support small intestine good/beneficial/friendly flora in adults
Maintain/support gastrointestinal system health in adults
Maintain/support gastrointestinal system health in children over 5 years of age
Maintain/support gastrointestinal system health in adolescents
Maintain/support immune system health in adults
Maintain/support healthy immune system function in adults

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Pack Size/Poison information



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium bifidum	1.35 billion CFU
Bifidobacterium breve	1.89 billion CFU
Bifidobacterium infantis	.15 billion CFU
Bifidobacterium lactis	.09 billion CFU
Bifidobacterium longum	2.7 billion CFU
Lactobacillus acidophilus	.3 billion CFU
Lactobacillus casei	4.65 billion CFU
Lactobacillus helveticus	6.6 billion CFU
Lactobacillus plantarum	7.8 billion CFU
Lactobacillus rhamnosus	3 billion CFU
Streptococcus thermophilus	1.5 billion CFU

Other Ingredients (Excipients)

ascorbic acid
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
disodium edetate
gellan gum
hypromellose
inulin
magnesium stearate
maltodextrin
microcrystalline cellulose
potable water
potassium acetate

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