



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	231001	Protectyn
ARTG entry for	Medicine Listed	
Sponsor	Immuron Ltd	
Postal Address	PO Box 655, Carlton, VIC, 3053 Australia	
ARTG Start Date	24/11/2014	
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 . Protectyn

Product Type	Single Medicine Product	Effective Date	9/08/2023
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Permitted Indications

- Decrease/reduce/relieve diarrhoea before eating in children over 5 years of age
- Decrease/reduce/relieve diarrhoea before eating in adults
- Helps reduce occurrence of diarrhoea before eating in adults
- Helps reduce occurrence of diarrhoea before eating in children over 5 years of age
- Decrease/reduce loose stools before eating in children over 5 years of age
- Decrease/reduce loose stools before eating in adults
- Helps enhance/promote healthy digestive system function before eating in children over 5 years of age
- Helps enhance/promote healthy digestive system function before eating in adults
- Enhance/promote healthy digestion before eating in children over 5 years of age
- Enhance/promote healthy digestion before eating in adults
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora before eating in adults
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora before eating in children over 5 years of age
- Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth before eating in adults
- Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth before eating in children over 5 years of age
- Maintain/support gastrointestinal system health before eating in adults
- Maintain/support gastrointestinal system health before eating in children over 5 years of age
- Helps enhance/promote gastrointestinal system health before eating in children over 5 years of age
- Helps enhance/promote gastrointestinal system health before eating in adults
- Maintain/support healthy gastrointestinal function before eating in children over 5 years of age
- Maintain/support healthy gastrointestinal function before eating in adults
- Maintain/support gastrointestinal mucosal membrane health before eating in children over 5 years of age
- Maintain/support gastrointestinal mucosal membrane health before eating in adults
- Aids/assists repair of gastrointestinal/gut wall lining before eating in children over 5 years of age
- Aids/assists repair of gastrointestinal/gut wall lining before eating in adults
- Decrease/reduce/relieve abdominal cramping before eating in children over 5 years of age
- Decrease/reduce/relieve abdominal cramping before eating in adults
- Helps decrease/reduce/relieve mild gastrointestinal tract inflammation before eating in children over 5 years of age

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- Helps decrease/reduce/relieve mild gastrointestinal tract inflammation before eating in adults
- Decrease/reduce/relieve gastrointestinal pain before eating in adults
- Decrease/reduce/relieve gastrointestinal pain before eating in children over 5 years of age
- Helps enhance/promote healthy liver function before eating in adults
- Helps enhance/promote healthy liver function before eating in children over 5 years of age
- Maintain/support healthy liver function before eating in adults
- Maintain/support healthy liver function before eating in children over 5 years of age
- Maintain/support liver health before eating in children over 5 years of age
- Maintain/support liver health before eating in adults
- Enhance/improve/promote immune defence/immunity before eating in children over 5 years of age
- Enhance/improve/promote immune defence/immunity before eating in adults
- Maintain/support healthy gastrointestinal immune function before eating in adults
- Maintain/support healthy gastrointestinal immune function before eating in children over 5 years of age

Indication Requirements

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

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If diarrhoea persists, seek medical advice

Products containing bovine colostrum powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children under the age of 12 months except on professional health advice.

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

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Not suitable for use in children under the age of 12 months except on the advice of a health professional. (or words to that effect)

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Tablet, uncoated
Route of Administration	Oral

Visual Identification

Active Ingredients

bovine colostrum powder 200 mg

Other Ingredients (Excipients)

- colloidal anhydrous silica
- croscarmellose sodium
- glucose
- magnesium stearate

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microcrystalline cellulose

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