



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	374256	Eagle Clinical SB Forte
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	6/09/2021	
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 Clinical SB Forte

Product Type	Single Medicine Product	Effective Date	6/09/2021
--------------	-------------------------	----------------	-----------

Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in children over 5 years of age
- Maintain/support general health and wellbeing in adolescents
- Helps reduce occurrence of diarrhoea in adolescents
- Helps reduce occurrence of diarrhoea in children over 5 years of age
- Helps reduce occurrence of diarrhoea
- Helps reduce occurrence of symptoms of traveller's diarrhoea in adults
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support healthy mucous linings of the digestive system in adolescents
- Maintain/support healthy mucous linings of the digestive system in children over 5 years of age
- Maintain/support intestinal good/beneficial/friendly flora in adolescents
- Maintain/support intestinal good/beneficial/friendly flora
- Maintain/support intestinal good/beneficial/friendly flora in children over 5 years of age
- Maintain/support small intestine good/beneficial/friendly flora in children over 5 years of age
- Maintain/support small intestine good/beneficial/friendly flora
- Maintain/support small intestine good/beneficial/friendly flora in adolescents
- Maintain/support gastrointestinal system health
- Maintain/support gastrointestinal system health in adolescents
- Maintain/support gastrointestinal system health in children over 5 years of age
- Maintain/support gastrointestinal mucosal membrane health
- Maintain/support gastrointestinal mucosal membrane health in adolescents
- Maintain/support gastrointestinal mucosal membrane health in children over 5 years of age
- Aids/assists repair of gastrointestinal/gut wall lining in adolescents
- Aids/assists repair of gastrointestinal/gut wall lining
- Aids/assists repair of gastrointestinal/gut wall lining in children over 5 years of age
- Maintain/support immune system health
- Maintain/support immune system health in children over 5 years of age

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Maintain/support immune system health in adolescents
Maintain/support healthy immune system function in adolescents
Maintain/support healthy immune system function in children over 5 years of age
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function in children over 5 years of age
Maintain/support healthy gastrointestinal immune function
Maintain/support healthy gastrointestinal immune function in adolescents
Helps stimulate a healthy immune system response in children over 5 years of age
Helps stimulate a healthy immune system response in adolescents
Helps stimulate a healthy immune system response
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children over 5 years of age
Maintain/support (state vitamin/mineral) within normal range in children over 5 years of age
Maintain/support (state vitamin/mineral) within normal range in adolescents
Maintain/support (state vitamin/mineral) within normal range

Indication Requirements

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 serious immunological diseases.

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.

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

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 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

For practitioner dispensing only.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

If symptoms persist, seek the advice of a healthcare professional.

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

colecalfiferol	.0062 mg
Saccharomyces cerevisiae (Boulardii)	250.0047 mg
zinc amino acid chelate	25 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

disodium edetate
dl-alpha-tocopherol
gellan gum
hypromellose
medium chain triglycerides
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide
sodium ascorbate
sorbitan monostearate
starch sodium octenyl succinate
sucrose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary