# Public Summary

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| **Summary for ARTG Entry:** | 227043 SB 500 |
| **ARTG entry for** | Medicine Listed |
| **Sponsor** | Spectrumceuticals Pty Ltd |
| **Postal Address** | 10/5 Narabang Way, BELROSE, NSW, 2085<br>Australia |
| **ARTG Start Date** | 19/08/2014 |
| **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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . SB 500

**Product Type** Single Medicine Product **Effective Date** 31/03/2020

**Permitted Indications**

Helps reduce occurrence of symptoms of traveller's diarrhoea

Maintain/support intestinal health

Maintain/support intestinal good/beneficial/friendly flora

Maintain/support gastrointestinal system health

**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).

**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).

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

**Additional Product information**

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

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| **Dosage Form** | Capsule, hard |
| **Route of Administration** | Oral |
| **Visual Identification** | |

| **Active Ingredients** | |
|---|---|
| **Saccharomyces cerevisiae (Boulardii)** | **500 mg** |

| **Other Ingredients (Excipients)** |
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| **disodium edetate** |
| **gellan gum** |
| **hypromellose** |
| **potable water** |
| **potassium acetate** |



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