Public Summary

Summary for ARTG Entry:	283003 SB Restore
ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia
ARTG Start Date	29/11/2016
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 Restore

Product Type Single Medicine Product **Effective Date** 9/01/2020

Permitted Indications

Maintain/support body mucous membrane health

Helps reduce occurrence of symptoms of traveller's diarrhoea

Maintain/support intestinal health

Maintain/support healthy digestive system function

Maintain/support healthy mucous linings of the digestive system

Maintain/support intestinal good/beneficial/friendly flora

Maintain/support healthy immune system function

Indication Requirements

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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

colecalciferol	**.0062 mg**
retinol acetate	**215 microgram**
Equivalent: vitamin A	187.45 RE/microgram
Saccharomyces cerevisiae (Boulardii)	**5 billion CFU**
selenomethionine	**15.63 microgram**
Equivalent: selenium	6.25 microgram
zinc citrate dihydrate	**23.44 mg**
Equivalent: zinc	7.5 mg

Other Ingredients (Excipients)

Acacia
butylated hydroxytoluene
colloidal anhydrous silica
disodium edetate
dl-alpha-tocopherol
gellan gum
hypromellose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide
sucrose

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