Public Summary

Summary for ARTG Entry:	321096 UltraBiotic 45
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	31/07/2019
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 . UltraBiotic 45

Product Type Single Medicine Product **Effective Date** 31/07/2019

Permitted Indications

Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
- Linked indication - Maintain/support general health and wellbeing
- Linked indication - Helps reduce occurrence of constipation
- Linked indication - Helps reduce occurrence of diarrhoea
- Linked indication - Decrease/reduce/relieve abdominal pain/discomfort

Maintain/support healthy digestive system function

Aid/assist digestion of lactose

Maintain/support digestive system health

Maintain/support intestinal good/beneficial/friendly flora

Helps maintain/support good/beneficial/friendly gut flora during antibiotic use

Help restore good/beneficial/friendly gut flora after antibiotic use

Decrease/reduce/relieve abdominal bloating/distention

Maintain/support immune system health

Maintain/support healthy immune system function

Indication Requirements

Label statement: If symptoms persist or worsen talk to your medical practitioner.

Product presentation must only refer to medically diagnosed IBS.

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

Label statement: Drink plenty of water (or words to that effect).

Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek

the advice of a healthcare professional before taking this product (or words to that effect).

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).

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

Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.

Product presentation must not refer to or imply weight loss.

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

No Warnings included on Record

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

Bifidobacterium animalis ssp lactis	**4.275 billion CFU**
Bifidobacterium bifidum	**225 million CFU**
Bifidobacterium breve	**1.35 billion CFU**
Lactobacillus acidophilus	**7.4 billion CFU**
Lactobacillus casei	**9.45 billion CFU**
Lactobacillus fermentum	**1.35 billion CFU**
Lactobacillus plantarum	**3.15 billion CFU**
Lactobacillus rhamnosus	**15.55 billion CFU**
Streptococcus thermophilus	**2.25 billion CFU**

Other Ingredients (Excipients)

ascorbic acid
dibasic potassium phosphate
disodium edetate
gellan gum
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
monobasic potassium phosphate
potable water
potassium acetate
silicon dioxide
sodium chloride
sucrose
trehalose dihydrate

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