Public Summary

Summary for ARTG Entry:	222399 Pro4-50 D-Lactate Free
ARTG entry for	Medicine Listed
Sponsor	Spectrumceuticals Pty Ltd
Postal Address	10/5 Narabang Way, BELROSE, NSW, 2085 Australia
ARTG Start Date	11/04/2014
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.

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 . Pro4-50 D-Lactate Free

Product Type Single Medicine Product **Effective Date** 11/04/2014

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

For the symptomatic relief of constipation. [Warnings S and LAX1 required / LAX2 required in certain circumstances]

May assist in the management of medically diagnosed irritable bowel syndrome

For the symptomatic relief of medically diagnosed irritable bowel syndrome

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Supplementation during pregnancy and whilst breastfeeding may support healthy immune function of the newborn after birth

Lactobacillus rhamnosus supplementation by expectant mothers prior to birth and may assist in healthy gastrointestinal colonisation of the newborn for the first few months of life

Lactobacillus rhamnosus and Bifidobacteria lactis taken during pregnancy and post natally whilst breastfeeding decreases the incidence of atopic dermatitis/allergy in children in their first years of life

Supports healthy gastrointestinal microflora after a course of antiobiotic

Lactobacillus rhamnosus is a commensal microorganism that inhabits the human intestinal mucosa, contributing to digestive function

Lactobacillus rhamnosus may provide temporary relief of diarrhoea

Lactobacillus rhamnosus colonise the urogenital and intestinal tracts and assist in restoring and maintaining urogenital flora/health

Bifidobacteria species found in the rectum/intestinal tract may contribute to the maintenance of normal healthy vaginal flora

Bifidobacterium lactis is a commensal microorganism that inhabits the human intestinal mucosa and contributes to healthy digestive function

Warnings

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

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).

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

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

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 breve	**5 billion CFU**
Bifidobacterium lactis	**15 billion CFU**
Bifidobacterium longum	**5 billion CFU**
Lactobacillus rhamnosus	**25 billion CFU**

Other Ingredients (Excipients)

hypromellose
magnesium stearate
microcrystalline cellulose
silicon dioxide