

SCHEDULING STATUS: Nutritional supplement (Act 54/1972)

PROPRIETARY NAME (AND DOSAGE FORM): INTESTIFLORA® Spray:

90 dosages per bottle.

COMPOSITION: Each squirt of the probiotic spray has a volume of approximately 250 µl (microliters) and contains 2 billion CFU (colony forming units) of a mixture of: *Lactobacillus acidophilus*, *Lactobacillus rhamnosus*, *Bifidobacterium bifidum* and *Bifidobacterium longum*.

PHARMACOLOGICAL ACTION: INTESTIFLORA® Spray contains a mixture of lyophilised probiotic bacteria namely, *Lactobacillus acidophilus*, *Lactobacillus rhamnosus*, *Bifidobacterium bifidum* and *Bifidobacterium longum* which are natural inhabitants of the human intestines. INTESTIFLORA® Spray is administered to restore the normal intestinal lactobacilli and bifidobacteria destroyed by broad-spectrum antibiotics, therefore limiting the overgrowth of pathogenic organisms. Administration of high doses of these bacteria helps to prevent diarrhoea associated with broad-spectrum antibiotic treatment.

INDICATIONS: **INTESTIFLORA®** “When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”:

CONTRA-INDICATIONS: None known

DOSAGE AND DIRECTIONS FOR USE: For adults: Treatment dose:

one squirt three times per day, preferably on an empty stomach,

30 minutes before meals, for one to two weeks. In conjunction with antibiotic therapy continue with the treatment for at least one week after the completion of the therapy.

Maintenance dose: one squirt once per day, preferably on an empty stomach, 30 minutes before meals.

For children 1 to 6 years old: one squirt per day;

7 to 14 years old: two squirts per day.

For children above 14 years: an adult dose is recommended.

SHAKE BOTTLE VERY WELL PRIOR TO APPLICATION

SIDE-EFFECTS AND SPECIAL PRECAUTIONS: Large doses may cause loose stools in some individuals.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT: Loose stools whereupon the administration of INTESTIFLORA® Spray should be discontinued temporarily.

PRESENTATION: Amber spray bottle with metered spray insert.

STORAGE INSTRUCTIONS: Store below 25°C

KEEP OUT OF REACH OF CHILDREN

DATE OF PUBLICATION OF THIS PACKAGE INSERT: July 2012

NAME AND BUSINESS ADDRESS OF MANUFACTURER:

The Name of the Applicant:

Bioflora® CC

Unit 29, The Tannery Industrial Park,

309 Derdepoort road, Silverton, 0002

Tel/Fax: +27 (0) 804 8703

E-mail: pieter@bioflora.co.za