

SCHEDULING STATUS: Nutritional supplement (Act 54/1972)

PROPRIETARY NAME (AND DOSAGE FORM): COMBIFORTE® 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 GG, Bifidobacterium bifidum and Bifidobacterium longum.

PHARMACOLOGICAL ACTION: COMBIFORTE® Spray contains a mixture of lyophilised probiotic bacteria namely, Lactobacillus acidophilus, Lactobacillus rhamnosus GG, Bifidobacterium bifidum and Bifidobacterium longum which are natural inhabitants of the human intestines. COMBIFORTE® 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: COMBIFORTE® Spray is indicated for the treatment of antibiotic-induced diarrhoea and other intestinal disorders as well as for the restoration of the naturally occurring bacterial intestinal flora.

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 COMBIFORTE® 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: October 2013

NAME AND BUSINESS ADDRESS OF MANUFACTURER:

Creative Care Solutions Medical (Pty) Ltd

Unit 8, Keymax Park

1006 Ergon Road, Lyttelton Ext 6      Reg No: 2003/022808/07

Centurion 0140, Gauteng;      Tel: +27 (0) 12 644 1584

P.O. Box 8142, Centurion, 0046      Fax: +27 (0) 12 644 1585

The Name of the Applicant:

Bioflora® CC

Unit 6, Keymax Park,

1006 Ergon rd, Lyttelton,

Centurion, 0157

Tel/Fax: 067 169 2597

E-mail: pieter@bioflora.co.za