

SCHEDULING STATUS: Nutritional supplement (Act 54/1972)

PROPRIETARY NAME (AND DOSAGE FORM): INFANTIFORTE capsules

COMPOSITION: Each capsule contains 12,9 mg consisting of *Bifidobacterium infantis* (in a lyophilised form), which yields not less than 1 billion (10^9) viable cells.

PHARMACOLOGICAL ACTION: INFANTIFORTE capsules contain cells of *Bifidobacterium infantis*, a species which is a natural inhabitant of the infant's intestinal tract.

INFANTIFORTE is administered to restore the normal intestinal bifidobacteria destroyed by antibiotics, in order to limit the overgrowth of pathogenic organisms in the intestines. Administration of high doses of these bacteria helps to prevent diarrhoea associated with antibiotic treatment.

INDICATIONS: INFANTIFORTE capsules are indicated for the treatment of antibiotic-induced diarrhoea and other intestinal disorders as well as the restoration of the naturally occurring bifidobacterial flora of the infant's intestinal tract.

CONTRA-INDICATIONS: None known

DOSAGE AND DIRECTIONS FOR USE: For infants 0 - 12 months:

Treatment dose: The contents of 1 capsule to be taken three times per day, suspended in a liquid or in a baby formulae, after cooling the liquid to body temperature.

In conjunction with antibiotic therapy continue with the treatment for at least one week after the completion of the therapy. In cases of acute diarrhoea the dosage can be increased to 2 capsules three times per day.

Maintenance dose: 1 capsule per day suspended in a liquid.

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 INFANTIFORTE should be discontinued temporarily.

IDENTIFICATION: White gelatine capsules containing white to cream coloured, granular material with a slight lactic acid smell.

PRESENTATION: 30 and 90 capsules in Securitainers.

STORAGE INSTRUCTIONS: Store below 8°C (in refrigerator or freezer)

KEEP OUT OF REACH OF CHILDREN.

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NAME AND BUSINESS ADDRESS OF MANUFACTURER:

Creative Care Solutions Medical (Pty) Ltd, Reg No 2003/022808/07

Unit 8, Keymax Park, 1006 Ergon Road, Lyttelton Ext 6, Centurion, Gauteng

Tel: (012) 644 1584

Fax: (012) 644 1585