

Logotype FFbaby – 1x

First bacterial flora for infants from the first hours of life

FFbaby contains composition of live bacteria of *Bifidobacterium* and *Lactobacillus* genus. The preparation is intended for the dietary management in order to determine appropriate composition of gastrointestinal tract bacterial flora of newborn infants. It is intended for infants who experienced conditions which interfered or delayed gastrointestinal colonization with beneficial bacteria, e.g. premature birth, birth by cesarean section, temporary or permanent not breast-feeding, antibiotic treatment.

Lack of appropriate colonization in the first days and weeks of life may cause dysfunction of infant gastrointestinal tract and may lead to development of intestinal inflammation, necrotizing enterocolitis (NEC) as well as sepsis.

Important information

FFbaby is a food for special medical purposes. It is dedicated for infants from the first hours of life. The preparation must be used under medical supervision, both in hospital and post-hospital conditions. Do not use parenterally.

The preparation is an incomplete foodstuff. It is not suitable for use as the sole source of nourishment.

FFbaby is recommended for infants:

- prematurely born,
- with low, very low and extremely low birth weight,
- born by cesarean section,
- born by women subject to perinatal antibiotic therapy,
- not breast-fed or fed with a delay,
- treated with antibiotics,
- fed with gastric tube,
- staying at hospital departments, especially without close contact with parents.

Properties

FFbaby contains two specially selected strains of live bacteria: *Lactobacillus rhamnosus* KL53A and *Bifidobacterium breve* PB04.

The following properties of these bacteria have been confirmed in *in vitro* and *in vivo* studies:

- ability to increase intestinal barrier integrity through the production of tight junction proteins,
- ability to produce substances with activity against: *Escherichia coli*, *Streptococcus agalactiae*, *Staphylococcus epidermidis*, *Staphylococcus aureus*, *Enterococcus faecalis*, *Clostridium difficile*,
- resistance to low stomach pH and bile salts, which enables bacteria to survive in gastrointestinal tract,
- adherence to epithelial intestinal cells, enabling bacterial colonisation of gastrointestinal tract,
- ability to block adherence sites of unfavorable microorganisms to intestinal epithelium – stronger with earlier administration,
- resistance to antibiotics typical for *Bifidobacterium* and *Lactobacillus* genus.

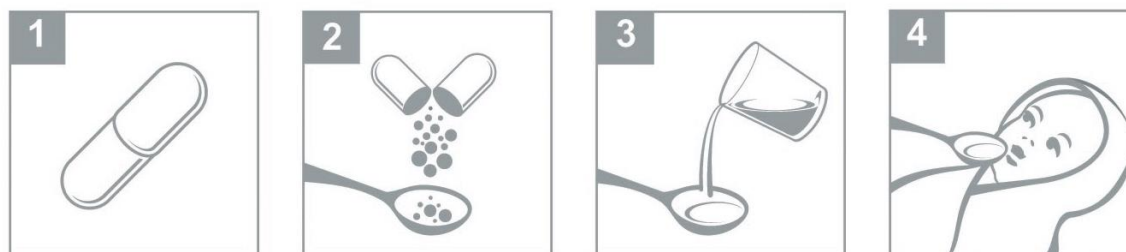
Safety and efficacy of using the strains contained in FFbaby have been shown in the studies.

Ingredients

One portion of powder contains: matlodextrin, bacterial strains: *Lactobacillus rhamnosus* KL53A and *Bifidobacterium breve* PB04, antioxidant – ascorbic acid.

Ingredients of shell of the capsule: gelatine, capsule colouring agent – titanium dioxide.

Dosage and method of preparation



- **ATTENTION! Do not administer to baby the shell of the capsule.**
- **Open the capsule**, take out the content of the capsule and dissolve in 1.5-3ml (1 teaspoon) tepid fluid, e.g. in boiled water at room temperature, breast milk or infant formula prepared in accordance with instruction.
- Administer two times daily from the first hours of life during period from 1 to 6 weeks.
- Product should be used directly after preparation (dissolved product can not be stored).

Oral administration

The product prepared in accordance with instruction should be given to baby in bottle with soother, with teaspoon or with little syringe (without needle!) on the internal side of the cheek.

Administration by gastric tube

Administration by gastric tube can be performed only in hospital conditions by medical staff.

The preparation should not be given in case of contraindications for enteral feeding (through gastrointestinal tract).

Nutritional and energetic value	Per 100 g of the product	Per 1 capsule
energy	1615 kJ/ 386 kcal	2,6 kJ/0,6 kcal
fat	0 g	0 g
of which		
— saturates	0 g	0 g
carbohydrate	93,9 g	<0,5 g
of which		
— sugars	32,6 g	<0,5 g

protein	1,9 g	<0,5 g
salt	0,38 g	<0,01 g
bacterial strains: <ul style="list-style-type: none"> • <i>Lactobacillus rhamnosus</i> KL53A • <i>Bifidobacterium breve</i> PB04 	613 million	1 million

Package contents

14 capsules to be opened - 239mg each. Net weight 3.3g.

Storage

Store at temperature 2°C - 8°C (in a refrigerator).

Keep out of reach of young children.

Protect against humidity.

Manufacturer

IBSS BIOMED S.A.

Al. Sosnowa 8

30 – 224 Krakow, Poland

Tel: +48 12 37 69 200

Fax: +48 12 37 69 205

e-mail: bdu@biomed.pl

Logo IBSS BIOMED S.A. – 1x

Date of preparation: May 2017

Pharma code: 259 IIIIIII