

# VIPLACTIN BABY

**Trade name:** Viplactin Baby.

**International Nonproprietary Name:** *Bacillus clausii*.

**Dosage form:** Powder for oral solution.

**Composition:** Each 1gm sachet contains:  
Bacillus Clausii 2 billion cfu

Excipients: Colloidal silicon dioxide, Lactose.

**Pharmacotherapeutic group:** Antidiarrheal microorganisms.

**ATC Code:** A07FA.

**Pharmacologic property:**

*Pharmacodynamics:*

*B. clausii* strains release antimicrobial substances in the medium. The release of these antimicrobial substances was observed during stationary growth phase and coincided with sporulation. These substances were active against Gram-positive bacteria, in particular against *Staphylococcus aureus*, *Enterococcus faecium*, and *Clostridium difficile*. The antimicrobial activity was resistant to subtilisin, proteinase K, and chymotrypsin treatment, whereas it was sensitive to pronase treatment. The evaluation of the immunomodulatory properties of probiotic *B. clausii* strains was performed in vitro on Swiss and C57 Bl/6j murine cells and it was demonstrated that these strains, in their vegetative forms, are able to induce NOS II synthetase.

*Bacillus clausii* possesses antibiotic resistance to a few antibiotics. This resistance has been shown to be chromosome encoded and not linked to transferable genetic elements.

Due to its antibiotic resistance, *Bacillus clausii* can be administered in the interval between two doses of antibiotics.

*Pharmacokinetics:*

*Bacillus clausii* spores survive transit through the human gastrointestinal tract. They can undergo germination, outgrowth and multiplication as vegetative forms. Administered orally, *Bacillus clausii* spores, due to their high-resistance to both chemical and physical agents, cross the barrier of the gastric juices reaching unharmed the intestinal tract where they are transformed into metabolically active vegetative cells. The microorganisms do not colonise the human intestine but have a transient presence. Spinosa *et al* (2000) inoculated intragastrically, two groups of mice with a single dose of 10<sup>9</sup> spores. Samples were taken from intestinal sites, lymph organs and blood at 4, 24 and 72 hours after inoculation. Spores of the inoculated *Bacillus* strains were found at the intestinal sites at 4 hours. They were largely excreted in the feces as spores, with their presence decreasing exponentially over 72 hours by when they were a 10<sup>th</sup> of the total spore count.

The administration of *Bacillus clausii* contributes to the recovery of the intestinal microbial flora altered during the course of microbial disorders of diverse origin.

**Indications for use:**

*Bacillus clausii*

⊗ Improve intestinal bacterial flora and help in prevention of disorders caused by intestinal

infections, intoxications, food disorders, unbalanced diet, use of antibiotics. *Bacillus clausii* sachets help restore the normal intestinal flora and hence fortifies the digestive system with healthy bacteria to promote overall digestive health.

⊗ Relieves Diarrhea, abdominal pain, gas.

**Contraindications:**

None known.

**Pregnancy and Lactation:**

It is preferable to check with your healthcare practitioner although generally regarded as safe.

**Dosage and direction for use:**

Take one sachet twice daily after meals or as directed by the physician.

*Directions for use:*

Should be administered orally mixed with water or beverage.

**Side effects:**

None known

**Overdose:**

Excessive doses of *Bacillus clausii* do not generally cause undesired effects. Do not exceed recommended doses.

**Drug Interactions:**

None known.

**Warnings & Precautions:**

Do not use if hypersensitive to the active ingredient or excipient. Keep out of reach of children.

*Effects on ability to drive and use machines:*

Not Available

**Presentation:**

1 gm powder for oral solution is packed in 1 sachet. Such 10 sachets are packed in one carton along with package insert.

**Storage:**

Keep in dry place, protected from light at a temperature below 30°C. Keep out of reach of children.

**Shelf life:**

24 months. Do not use after expiry date.

**Distribution Condition:**

Non-prescribed medicine.

**Globally marketed by:**

BELINDA LABORATORIES LLP.  
United Kingdom



**The holder of Trade Mark and**

**Marketing Authorization:**

BELINDA LABORATORIES LLP.  
London, United Kingdom

**Manufactured by:**

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