For the Use of a Registered Medical Practitioner Only

1. Generic Name & Brand Name

Bacillus clausii Spores Suspension

BENEGUT®

2. Qualitative and Quantitative Composition

Each 5ml oral suspension contains:

Bacillus clausii spores IHS	2×10^9 spores
Purified Water I.P.	q.s.

3. Dosage Form and Strength

Refer section 1& 2

4. Clinical Particulars

4.1 Therapeutic Indication

Benegut is indicated for the treatment of alterations of the intestinal bacterial flora.

4.2 Posology and Method of Administration

Adult: 2 – 3 units a day
Children: 1 – 2 units a day
Infants – 1-2 units a day
The doses should be given at regular intervals of at least 3-4 hours.

Instructions Before Administering the Medicine

Being a suspension of highly complex entities from microbes and in high number volume (2 billion spores), corpuscles or tiny particles (lumpy mass) may be seen in each unit pack. However, this is a product characteristic and is due to aggregates of *B. clausii* spores. To obtain a uniform suspension, shake the unit pack well before use. To open unit pack, unscrew and remove the top of the cap.

Instructions on How to Administer the Medicine

Take the contents as it is or diluted in tea, milk, fruit juices etc. Once open, the drug should be consumed without delay, to avoid contamination or deterioration of the suspension. This medicine is for oral use only. Do not inject it or administer in any other manner. During treatment with antibiotics, it should be taken during the interval between antibiotic doses.

4.3 Contraindications

Should not be used in individuals hypersensitive to the active substance or to any of the excipients.

4.4 Special Warnings and Precautions for Use

This medicine is for oral use only. Do not inject or administer in any other way.
Do not exceed the doses indicated without consulting your doctor. Use only for a short period of treatment.
During antibiotic therapy, the product should be administered in the interval between one dose of antibiotic and the next. Contact your doctor if the condition worsens after 2-3 days of usage.
Keep out of the reach of children.

4.5 Drug Interactions

There are no known food or drug interactions. Please inform your doctor if you are taking any other medications.

4.6 Use in Special Population
Pregnancy and Lactation
No contraindications.

4.7 Effects on Ability to Drive and Use Machines
The drug does not interfere with the ability to drive or use machinery.

4.8 Undesirable Effects
Hypersensitivity reactions, including rash and urticaria have been reported. If any undesired effect is observed, promptly report to your doctor.

4.9 Overdose
Excessive doses of Benegut do not generally cause undesired effects. Consult your doctor in case of overdosage.

5. Pharmacological Properties
5.1 Mechanism of action
Probiotics are intended to assist the body's natural gut microbiota. The potential mechanisms by which probiotics exert their action include production of pathogen-inhibitory substances, inhibition of pathogen attachment, inhibition of the action of microbial toxins, stimulation of immunoglobulin A, and trophic effects on intestinal mucosa.
5.2 Pharmacodynamic Properties
BENEGUT® is a preparation consisting of a suspension of Bacillus clausii spores, normal inhabitants of the intestine, with no pathogenic properties.
The administration of BENEGUT® contributes to the recovery of the intestinal microbial flora altered during the course of intestinal microbial imbalance of diverse origin, due to the action of the Bacillus clausii. Furthermore, since the Bacillus clausii is capable of producing various vitamins, in particular group B vitamins, it contributes to correcting the dysvitaminosis caused by antibiotics and chemotherapeutic agents in general.
BENEGUT® makes it possible to obtain an aspecific antigenic and antitoxic action, closely connected with the metabolic action of the B. clausii.
In addition, the high degree of heterologous resistance to the antibiotics, induced artificially, provides for the creation of the therapeutic basis for preventing the alteration of the intestinal microbial flora, following the selective action of antibiotics, especially the broad-spectrum ones, or to re-establish its balance.
5.3 Pharmacokinetic properties
Administered orally, Bacillus clausii spores, due to their high resistance to both chemical and physical agents, cross the barrier of the acid gastric juices reaching, unharmed, the intestinal tract where they are transformed into metabolically active vegetative cells.

6. Nonclinical Properties
6.1 Animal Toxicology or Pharmacology
In an in vitro experimental study, the cytotoxic effects of C. difficile and Bacillus cereus were prevented by proteolytic compounds secreted by the probiotic B. clausii strain O/C; the hemolytic effect of B. cereus was also inhibited. The proteolytic enzyme activity was 4-fold higher during sporulation than during vegetative cell growth; after purification, the enzymatic-specific activity of the purified protease was 13-

fold higher than the spore supernatant activity. The increased cell detachment and loss of mitochondrial dehydrogenase induced by C. difficile toxins was completely prevented in Vero cells by coincubation with B. clausii in a time-dependent manner; similar results were observed in Caco-2 cells.

7. Description

Benegut is supplied for oral administration, as an oral suspension of *Bacillus clausii*. Each 5ml oral suspension contains *Bacillus clausii* spores IHS 2 x 10^9 spores.

8.Pharmaceutical Properties

8.1 Incompatibilities

Not applicable

8.2 Shelf Life

Refer Pack

8.3 Packaging Information

Refer Pack

8.4 Storage and Handling Instructions

Refer Pack

9.0 Patient Counseling Information

Benegut® is an oral suspension containing Polyantibiotic resistant spores of Bacillus clausii.

What is Benegut®?

Benegut® is a probiotic which is useful for the management of imbalance of intestinal bacterial flora due to diverse causes.

Why is it used?

Benegut® is used for managing the alterations of intestinal bacterial flora. Benegut® restores the equilibrium of the intestinal flora, changed during diarrhoea or in the course of therapy with antibiotics or chemotherapy, contributing to correct the consequent dysvitaminosis (imbalance of production and assimilation of vitamins).

How to use Benegut®?

Adult: 2 – 3 units a day

Children: 1 – 2 units a day

Infants – 1-2 units a day

Caution: Do not exceed the instructed doses without the advice of your healthcare practitioner.

Instructions for use:

It is necessary to shake the bottle before use. To open the bottle, rotate the upper part and detach it. Take the entire content as such or dilute it in water or other drinks (for example: Milk, orange juice).

Once open, consume within a short time to avoid contamination of the suspension.

When should it not be used?
Hypersensitivity towards the components or other closely related substances.

Can it be taken during pregnancy and lactation?
Benegut® can be used during pregnancy and breast feeding.

Precautions for use:
During antibiotic therapy, the product should be administered in the interval between one dose of the antibiotic and the next.

It is important to know that:
The possible presence of corpuscles visible in the vials of Benegut® is due to aggregates of Bacillus clausii spores and does not, therefore, indicate that the product has undergone changes.

What to do if you have taken excessive dose of Benegut®?
Excessive doses of Benegut® do not produce any side-effects. However, it is better to follow the recommended dose. Please report any adverse events to your healthcare provider. You may also report side effects by writing to webmasterindia@abbott.com.

Side effects:
No side effects have been reported with the use of Benegut®. However, it is important to communicate any undesired effects. Please report any adverse events to your healthcare provider. You may also report side effects by writing to webmasterindia@abbott.com.

What to do if you have forgotten to take one or more doses?
While there are no particular problems associated with missing a dose, it is advisable to complete the daily dose for best results. Remember that the correct and careful administration increases it's effectiveness.

Expiry:
Caution: Do not use Benegut® after the expiry date on the label.

If you have any further questions on the use of this medicine, ask your doctor or healthcare provider.

10.Details of Manufacturer
Refer pack for manufacturer details.

Marketed By:
Abbott India Limited
Angel Space, Lifestyle Bldg. No. D-4,
Gala No. 7 to 10 & 17 to 20 Ground Floor,
107 to 110 & 117 to 120 First Floor,

Version 6.0, dated 13th May 2024
Replaces Version: 5.0, dated 25th May 2022

Pimplas Village, Dist. Thane,
Bhiwandi - 421 302, India

® Registered Trademark Under License from Virchow Biotech Private Limited.

11. Details of Permission or License Number with Date
Refer pack for permission/license details.

12. Date of Revision
Version 6.0, dated 13/05/24

For product complaints and queries please write to
webmasterindia@abbott.com

Source : PI of Clasipro (Mfd by Virchow Biotech Pvt. Ltd)
Enterogermina Pack Insert (Sanofi)