

Bacillus clausii spores suspension

Enterogermina®

Bacillus clausii (O/C, N/R, SIN and T)

SANOFI 

Patient information leaflet

Enterogermina® is an oral suspension containing polyantibiotic-resistant spores of *B. clausii*

Composition

1 mini bottle contains:

Main active element: 2 billion Spores of polyantibiotic-resistant *Bacillus clausii**

Excipient: Water Purified Ph. Eur

(*Polyantibiotic-resistant means resistant to a certain number of antibiotics. It is an extremely important characteristic of Enterogermina® that allows it to be administered during antibiotic treatment with penicillin, cephalosporins, tetracycline, macrolides, aminoglycosides, novobiocin, chloramphenicol, thiamphenicol, lincomycin, isoniazid, cycloserine, rifampicin, nalidixic acid and piperidic acid).

Presentation

Enterogermina® is presented in the form of an oral suspension in water and is available as 5 ml mini bottles.

One pack contains 10 ready-to-drink mini bottles.

What is Enterogermina®?

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

Why is it used?

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

How to use Enterogermina®?

Dosage:

Adults: from 2 to 3 mini bottles a day

Children: from 1 to 2 mini bottles a day

Infants: from 1 to 2 mini bottles a day

Caution: Do not exceed the indicated doses without the advice of the physician.

Administration

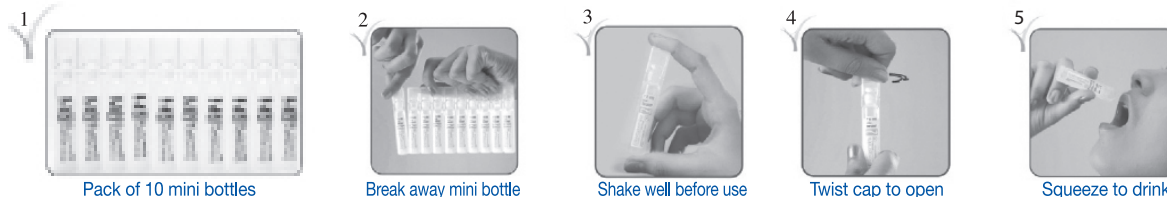
Take Enterogermina® at regular intervals during the day.

Consult the physician if the condition recurs or if you have noticed any recent change in the nature of symptoms. The medicinal product is for oral use only. Do not inject or administer in any other way.

Instructions for use

It is necessary to shake the mini bottle before use. To open the mini bottle, rotate the upper part and detach it. Take the content as such or dilute it in sweetened water, milk, tea, orange juice.

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



When must it not be used?

Hypersensitivity towards the components or other closely related substances.

Can it be taken during pregnancy and lactation?

If you are pregnant or planning to become pregnant, talk to your doctor about using Enterogermina®. If you are breastfeeding or planning to breastfeed, talk to your doctor about using Enterogermina®.

Precautions for use

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

There have been reports of bacteremia, septicemia or sepsis in patients taking *Bacillus clausii* who are immunocompromised or are hospitalized due to a serious illness. Enterogermina® should be used in these patients only if the potential benefits outweigh the potential risks.

It's important to know that-

The possible presence of corpuscles visible in the mini bottles of Enterogermina® is due to aggregates of *Bacillus clausii* spores and does not, therefore, indicate that the product has undergone any changes.

What to do if you have taken an excessive dose of Enterogermina®?

Excessive doses of Enterogermina® do not produce side effects. However, it is better to follow the recommended doses.

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 its therapeutic effect.

Side effects

During post marketing experience, hypersensitivity reactions, including rash, urticaria and angioedema have been reported. Bacteremia, septicemia or sepsis in immunocompromised patients or those hospitalized due to a serious illness.

Expiry

The un-opened mini bottles of Enterogermina® are stable for a period of 24 months.

Caution: Do not use the medicine after the expiry date on the label.

Storage

Do not store above 30 °C.

KEEP OUT OF THE REACH OF CHILDREN.

Manufactured by:

Sanofi S.r.l. - Viale Europa, 11 - 21040 - Origgio (VA) – Italy

Importer: Sanofi Healthcare India Private Limited, Gala No. 4, Ground Floor, Building No. B1, Citylink Warehousing Complex, S No.121/10/A,121/10/B & 69, NH3, Vadape. Tal: BHIWANDI - 16(THANE Z5) Pin :421302.

Source:

1. **Bacillus clausii CCSI v3 LRC dated 12 Mar 2020**

2. **SmPC dated January 2012**

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For more information, log onto www.enterogermina.in or contact us at 1800-22-2295

Or email: Enterogermina.india@sanofi.com