

Spores of polyantibiotic-resistant *Bacillus clausii*
Enterogermina® 2 billion/5 mL oral suspension

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*

What Enterogermina® contains?

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 pipemidic acid).

What Enterogermina® looks like and contents of the pack?

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 medicine consisting of a four strain (SIN, O/C, T, N/R) spore suspension of *Bacillus clausii*, normally present in the intestine, without disease-causing capacity (without pathogenic ability).

Why is it used?

Enterogermina® is used for:

- the prevention and treatment of intestinal disorders related to the alteration in intestinal flora, that manifest themselves as diarrhea, abdominal pain and increase of air in the bowel (intestinal dismicrobism), and vitamin deficiencies in the body resulting from the imbalance of intestinal flora (endogenous avitaminosis).
- coadjuvant treatment to restore intestinal microbial flora altered during treatment with antibiotics or chemotherapy.
- the treatment of acute and chronic gastro-intestinal diseases of infants caused by poisoning or alteration of the normal balance of intestinal bacterial flora, that manifest themselves as diarrhea, abdominal pain and increase of air in the bowel (intestinal dismicrobism), or vitamin deficiencies in the organism (avitaminosis).

How to take Enterogermina®?

Take this medicine exactly as described in this leaflet or as instructed by your doctor or pharmacist. Check with your doctor or pharmacist if you have any doubts.

Take Enterogermina® at regular intervals during the day.

The recommended doses are:

Adults: 2-3 mini bottles per day

Children: 1-2 mini bottles per day

Infants: 1-2 mini bottles per day
unless prescribed otherwise by the doctor.

Administration at regular intervals, Take the mini bottle as it is or dilute it in water or other beverages (e.g., milk, tea, orange juice).

Warning: do not exceed the indicated doses without your doctor's advice. Use only for short periods of treatment.

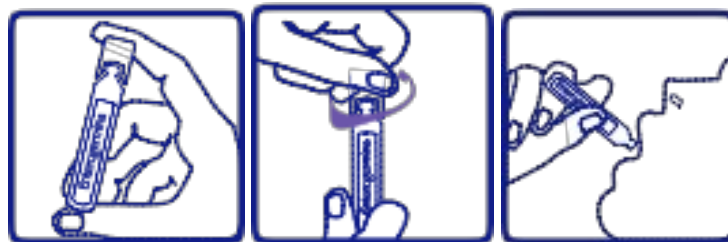
Consult your doctor if the disorder occurs repeatedly or if you have noticed a recent change of any kind in its characteristics.

Instructions for use

This medication is for oral use only. Do not inject or administer in any other way (see "Warnings and Precautions").

Shake before use. To open the mini bottles, unscrew the top part and remove it. Take the contents as it is or dilute it in water or any other beverage (for eg.: milk, tea, orange juice).

Once open, take the medicine within a short period of time to avoid the alteration of medicine.

**When must it not be used?**

Hypersensitivity to the active substance or to any of the excipients.

What you need to know before you take Enterogermina®**Do not take Enterogermina®**

- if you are allergic to spores of polyantibiotic-resistant *Bacillus clausii* or any of the other ingredients of this medicine

Warnings and precautions

Talk to your doctor before taking Enterogermina®

- if your doctor informed you that your immune system may be weakened (reduced body natural defences) (see section Side Effects).
- before giving Enterogermina® to a pre-term infant.

This medication is for oral use only. Do not inject or administer through other routes. Improper use of the medicine has resulted in severe anaphylactic reactions such as anaphylactic shock.

During treatment with antibiotics, ingest Enterogermina[®] between one administration and the other of the antibiotic.

If you notice the possible presence of corpuscles, or of tiny particles in the Enterogermina[®] mini bottles, that does not mean that the product has been impaired, as these are simply clusters of *Bacillus clausii* spores.

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.

Other medicines and Enterogermina[®]

Inform your doctor or your pharmacist if you are taking, have recently taken or could take any other medication, including over-the-counter medication.

No disorders (interactions) are envisaged concerning the association between Enterogermina[®] and other medicines.

Pregnancy and breast-feeding

If you are pregnant, may be pregnant, are planning to become pregnant, or are breast-feeding, talk to your doctor or pharmacist before taking this medicine.

During pregnancy and breastfeeding, take this medicine only when absolutely necessary and under the supervision of your doctor.

Fertility

No data are available on the effect of Enterogermina[®] on human fertility.

Driving and using machines

Enterogermina[®] has no or negligible influence on the ability to drive or operate machinery.

If you take more Enterogermina[®] than you should

Excessive doses of Enterogermina[®] do not produce side effects. However, it is better to follow the recommended doses. In case of accidental ingestion/administration of an overdose of Enterogermina[®] immediately notify your doctor or go to the nearest hospital.

If you forget to take Enterogermina[®]

Do not take a double dose to make up for a missed dose.

Proper and regular intake of this medicine promotes a better therapeutic effect.

If you stop taking Enterogermina[®]

No particular effects have been reported, apart from the lack of therapeutic effect.

If you have any doubts regarding the use of this medicine, speak to your doctor or pharmacist.

Possible Side effects

As with all medicines, this medicine can cause undesirable effects, although not everyone is affected.

Contact your doctor immediately if you notice any of the following serious side effects:

Limited and mostly temporary swelling (hours or days) of the skin or mucous membranes, accompanied or not by itching (angioedema). When localized to the face, lips and throat it can make swallowing and breathing difficult.

Other side effects include:

Unknown frequencies side effects (may affect less than 1 in 10,000 people):

- allergic reactions (hypersensitivity), including skin rash and urticaria.
- In case of reduced body's defence mechanisms or serious illness and you are taking Enterogermina[®], *Bacillus clausii* may be found in your blood and may lead to a serious blood infection (see section Warning and precautions).

Reporting of side effects

If you experience any undesirable effects, including those not listed in this leaflet, please speak to your doctor or pharmacist.

By reporting undesirable effects, you can help provide more information on the safety of this medicine.

Expiry

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

How to store Enterogermina[®]

Do not store above 30 °C.

KEEP OUT OF THE REACH OF CHILDREN

Manufactured by:

Opella Healthcare Italy s.r.l., Viale Europa, 11 - 21040 - Origgio (VA) – Italy

Importer: Sanofi Healthcare India Private Limited, Gala No.4, Ground Floor, Building No B1, City Link Warehousing Complex, S No. 121/10/A, 121/10/B And 69, NH3 Vadape Tal- Bhiwandi 16, Thane Z5, Pin :421302.

Source:

1. Italian PIL dated Feb 2021
2. PI of Enterogermina[®] updated November 2022

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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

