

Enterogermina[®] Oral Suspension

Spores of poly-antibiotic resistant *Bacillus clausii* (2 billion/ 5 ml)

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What Enterogermina is used for

Enterogermina is a medicine consisting of spore of poly-antibiotic resistant *Bacillus clausii*, normally present in the intestine, without disease-causing capacity (without pathogenic ability).

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 Enterogermina works

Enterogermina re-establishes the balance of the intestinal flora that has undergone alterations during treatment with antibiotics or chemotherapeutic agents, contributing to correcting the subsequent dysvitaminosis (that is, disorders in the production and assimilation of vitamins).

“Poly-antibiotic resistant” means resistant to a certain number of antibiotics.

This is an extremely important characteristic of ENTEROGERMINA, which makes it possible to take it even during treatment with antibiotics, with the aim of preventing imbalance of the intestinal flora caused by the antibiotics themselves (penicillins, cephalosporins, tetracyclines, macrolides, novobiocin, aminoglycosides, chloramphenicol, thiamphenicol, lincomycin, isoniazid, cycloserine, rifampicin, nalidixic acid and piperimidic acid).

Before you use Enterogermina

-When you must not use it

if you are allergic (hypersensitive) to spores of poly-antibiotic resistant *Bacillus clausii* or any of the other ingredients.

-Before you start to use it

Talk to your doctor or pharmacist before taking Enterogermina:

- if your doctor informed you that your immune system may be weakened (reduced body natural defences)
- 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. If you notice the possible presence of corpuscles, or of tiny particles in the bottles of ENTEROGERMINA, this does not mean that the product has been impaired, as these are simply clusters of the *Bacillus clausii* spores.

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.

-Taking other medicines

During therapy with antibiotics, ENTEROGERMINA should be administered in the interval between one dose of antibiotic and the next. There are no known medicinal products or foods that can modify the effect of ENTEROGERMINA.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to use Enterogermina

-How much to use

Dosage

Adults: 2 - 3 bottles per day.

Children: 1 - 2 bottles per day.

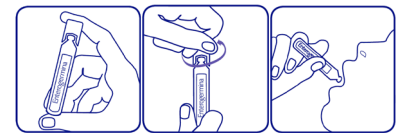
Breast-feeding infants: 1 - 2 bottles per day.

Important: do not exceed the recommended doses without first consulting a doctor

Method of administration

This product is for oral use only. Do not inject or administer in any other way.

The bottle should be shaken before use. To open the bottle, twist the upper part and break off.



Swallow the content of the bottle as it is or dilute it in water or some other beverage (e. g. milk, tea, orange juice). Once opened, the product should be used within a short space of time to avoid pollution of the suspension

-When to use it

Take ENTEROGERMINA at regular intervals during the day.

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

-How long to use it

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

-If you forget to use it

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 use too much (overdose)

In case of accidental ingestion/administration of an overdose of Enterogermina, immediately notify your doctor or go to the nearest hospital.

-If you stop taking Enterogermina

No particular problems have been reported, apart from a lack of therapeutic effect.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

-Things you must do

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

-Things you must not do

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.

-Things to be careful of

Driving and operating machinery: Enterogermina has no or negligible influence on the ability to drive or operate machinery.

The intestinal bacterial flora constitutes a real defensive barrier against harmful bacteria. Its balance can be upset by intestinal infections, poisoning, food disorders, changes in diet or use of antibiotics. Talk to your doctor if you do not notice any improvements or if you notice a worsening of symptoms after a brief period of treatment.

Side Effect

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 undesirable 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.

If any of the undesired effects gets serious, or if you notice any undesired effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Enterogermina

-Storage

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Shelf life: see the expiry date printed on the package.

Important: Do not use this medicine after the expiry date which is stated on the package after "Exp.". The expiry date refers to the last day of that month. The expiry date applies to the product when it is in an intact, properly stored package.

-Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Enterogermina oral suspension is whitish, opalescent, liquid.

It is packed in a minibottle.

-Ingredients:

-Active ingredients:

Each 5ml minibottle contains 2 billion spore of poly-antibiotic resistant Bacillus clausii

-Inactive ingredient: purified water.

-MAL Numbers:

MAL12085088X

Manufacturer

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Product Registration Holder

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