

Enterogermina® 2 billion/5 ml oral suspension

Spores of antibiotic multi-resistant *B. clausii*

sanofi aventis

BEFORE TAKING THIS PRODUCT PLEASE READ ALL THE INFORMATION CONTAINED IN THE LEAFLET CAREFULLY

This is a medicinal product for self-medication that you can use to treat mild, transitory disturbances that are easily recognisable and resolvable without needing to seek medical advice.

It can therefore be bought without a prescription, but should be used correctly in order to guarantee its efficacy and minimise the undesired effects. For further information and advice, ask the pharmacist.

Seek medical advice if the problem does not clear up after a short period of treatment.

In this leaflet:

1. What ENTEROGERMINA is and what it is used for
2. Before you take ENTEROGERMINA
3. How to take ENTEROGERMINA
4. Possible side effects
5. How to store ENTEROGERMINA
6. Further information

1. WHAT ENTEROGERMINA IS AND WHAT IT IS USED FOR

ENTEROGERMINA is an intestinal antidysmicrobial agent, i.e. it contains anti-diarrhoeal microorganisms and is therefore a drug for the treatment of alterations in the bacterial flora of the intestine.

ENTEROGERMINA is used to treat and prevent alterations of the intestinal bacterial flora. It 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).

ENTEROGERMINA can also be used in babies to treat

acute and chronic gastrointestinal disorders, whether they be caused by intoxication or by alterations in the intestinal flora with imbalance in the production and assimilation of vitamins.

2. BEFORE YOU TAKE ENTEROGERMINA

If one notes the presence of corpuscles, that is to say minute particles, in the bottles of ENTEROGERMINA, this does not mean that the product has undergone any changes; they are just aggregates of the *Bacillus clausii* spores.

Health education notes

The intestinal bacterial flora constitutes a true defence barrier against harmful bacteria. Its balance can be disturbed by intestinal infections, intoxication, alimentary disorders, changes in diet, the use of antibiotics. This imbalance makes itself manifest with diarrhoea, abdominal pain, increased amounts of air in the bowel.

Do not take ENTEROGERMINA

- if you are allergic (hypersensitive) to the active substance or any of the other ingredients.

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.

Pregnancy and breast-feeding

ENTEROGERMINA may be used during pregnancy and while breast-feeding.

3. HOW TO TAKE ENTEROGERMINA

Dosage

Adults: 2 - 3 bottles per day.

Children: 1 - 2 bottles per day.

Babies: 1 - 2 bottles per day.

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

Method and route 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.

Frequency of administration

Take ENTEROGERMINA at regular intervals during the day.

Consult your doctor if the problem continues to reoccur or if you have noted any recent change in its characteristics.

Duration of treatment

Important: use only for short periods of treatment.

If you take more ENTEROGERMINA than you should

Excessive doses of ENTEROGERMINA do not normally produce any side-effects. It is best, however, to stick to the recommended doses.

If you forget to take ENTEROGERMINA

There are no particular problems. It should be remembered, however, that correct and regular administration aids the therapeutic effect.

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ENTEROGERMINA can cause side effects, although not everybody gets them.

Hypersensitivity reactions including rash and urticaria have been reported in post-marketing experience.

Following the instructions given on this package leaflet reduces the risk of undesired effects.

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.

5. HOW TO STORE ENTEROGERMINA

Store at a temperature no higher than 30° C.

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

Important: do not use the product after the "use by" date indicated on the container. This date refers to the product in its original unopened packaging, correctly stored.

KEEP THE MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN

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.

It is important to always have the information regarding the medicine at hand, so keep both the packet and the package leaflet.

6. FURTHER INFORMATION

What ENTEROGERMINA contains

- The active substance is: spores of antibiotic multi-resistant* *Bacillus clausii*.

Each bottle contains 2 billion spores of antibiotic multi-resistant* *Bacillus clausii*.

- The other ingredient is: purified water.

* "Antibiotic multi-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, aminoglycosides, novobiocin, chloramphenicol, thiamphenicol, lincomycin, isoniazid, cycloserine, rifampicin, nalidixic acid and piperimidic acid).

Contents of the pack

Boxes containing 10 or 20 5-millilitre bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last approved

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Oral use
Do not inject

