

ENTEROGERINA 2 billion hard capsules

Spores of poly-antibiotic resistant *Bacillus clausii*

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 Spores of poly-antibiotic resistant *Bacillus clausii*.

ENTEROGERMINA supports the balance of the beneficial bacteria in the digestive tract.

2. BEFORE YOU TAKE ENTEROGERMINA

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 hard capsules per day.

Children: 1 - 2 hard capsules per day.

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

Do not use the product for children below 12 years. For children from 2 months to 12 years use Enterogermina Oral Suspension bottles.

Method of administration

Swallow the hard capsules with a sip of water or some other beverage.

Especially with very young children, in the event of their having difficulty in swallowing the hard capsules, it is better to use the oral 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.

To report any side effect(s):

Saudi Arabia

National Pharmacovigilance & Drug Safety Centre (NPC):

Fax: +966-11-205-7662

Toll free phone: 8002490000

E-mail: npc.drug@sfda.gov.sa

Website: www.sfda.gov.sa/npc

Sanofi - Pharmacovigilance: KSA_Pharmacovigilance@sanofi.com

5. HOW TO STORE ENTEROGERMINA

Do not store above 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 poly-antibiotic resistant*

Bacillus clausii.

Each hard capsule contains 2 billion spores of poly-antibiotic resistant* *Bacillus clausii*.

- The other ingredients are: heavy kaolin, microcrystalline cellulose, magnesium stearate, gelatin, titanium dioxide (E171), purified water.

* *“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, aminoglycosides, novobiocin, chloramphenicol, thiamphenicol, lincomycin, isoniazid, cycloserine, rifampicin, nalidixic acid and pipemidic acid).*

Contents of the pack

Boxes containing 12 or 24 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

sanofi S.p.A.

Viale L. Bodio, 37 / B - IT-20158 Milan (Italy)

Manufacturer

sanofi S.p.A.

Viale Europa, 11

21040 Origgio (VA) - Italy

This leaflet was last approved in

March 2012.