

Package leaflet: information for the patient

ENTEROGERMINA 6 billion/2 g powder for oral suspension

Spores of polyantibiotic-resistant *Bacillus clausii* – oral use

Read this leaflet carefully before you start taking this product as it contains important information for you.

Always take this product exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- If you would like more information or advice, ask your doctor or pharmacist.
- If you experience any of the undesirable effects, including effects not listed in this leaflet, speak to your doctor or pharmacist. See section 4.
- 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.

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1. Enterogermina and what it is used for

Enterogermina is a Spores of polyantibiotic-resistant *Bacillus clausii*

Enterogermina is used in adult patients for:

- Support the balance of the beneficial bacteria in the digestive tra

Health education notes

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. This imbalance manifests itself as diarrhoea, abdominal pain and an increase in air in the intestine.

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.

2. What you need to know before taking Enterogermina

Do not take Enterogermina

- if you are allergic to spores of polyantibiotic-resistant *Bacillus clausii* or any of the other ingredients of this product (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Enterogermina.

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

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

Children and adolescents

This product is indicated only for adult patients.

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 lactation

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 product.

Enterogermina may be used during pregnancy and lactation.

Driving and operating machinery

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

3. How to take Enterogermina

Take this product 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.

The recommended dose is:

Adults: 1 sachet per day.

Dissolve the contents of the sachet in water.

This product is for oral use only (see "Warnings and Precautions").

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.

If you take more Enterogermina than you should

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 product 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 product, speak to your doctor or pharmacist.

4. Possible undesirable effects

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

There have been reports of allergic reactions (hypersensitivity), including skin rash, urticaria and angioedema.

To report any side effect(s):***Saudi Arabia:***

The National Pharmacovigilance and Drug Safety Centre (NPC)

Fax: +966-11-205-7662

Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.

Toll free phone: 8002490000

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

Website: www.sfd.gov.sa/npc

Other GCC States:

- Please contact the relevant competent authority.

5. How to store Enterogermina

Keep the product out of the reach and sight of children.

Do not use this product 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.

Do not Store above 30°C in a dry place.

This product should not be thrown out in wastewater or put in household rubbish. Ask your pharmacist how to dispose of products which you are no longer taking. This will help to protect the environment.

6. Package contents and other information**Enterogermina contents**

- The active substance is spores of polyantibiotic-resistant *Bacillus clausii*. Each sachet contains 6 billion spores of polyantibiotic-resistant *Bacillus clausii*.
- The other components are: heavy kaolin, microcrystalline cellulose, mannitol, saccharin sodium, citrus aroma, colloidal anhydrous silica.

Description of what Enterogermina looks like and package contents

Enterogermina comes in form of powder for oral suspension.

Packages containing 10 or 20 sachets.

Marketing Authorisation Holder

Sanofi S.p.A. – Viale L. Bodio, 37/b – IT – 20158 Milano (Italy)

Manufacturer

Sanofi S.p.A. – Viale Europa, 11 – IT – 21040 Origgio (Va) Italy

This package leaflet was last revised in December 2015