ENTEROGERMINA 2 thousand million / 5ml
Oral suspension
ENTEROGERMINA 2 thousand million, rigid capsules

Spores of multiantibiotic-resistant *B. clausii*

**Before use, read carefully all the information given on this package leaflet**

This is a self-medication product that you can use to cure clearly recognizable, mild and transient disorders that can be resolved without any need for medical advice.

It can therefore be purchased without a prescription but must be used correctly to ensure its efficacy and reduce the risk of undesired effects.

For more information and advice, ask at your chemist’s.

Consult a doctor if the disorder is not resolved after a short period of treatment.

**Composition**

Each bottle contains:

- active ingredient: 2 thousand million **spores of multiantibiotic-resistant Bacillus clausii**
- excipient: purified water

Each capsule contains:

- active ingredient: 2 thousand million **spores of multiantibiotic-resistant Bacillus clausii**
- excipients: kaolin, microcrystalline cellulose, magnesium stearate, gelatin, titanium dioxide (E171), purified water.

Multiantibiotic-resistant means resistant to several different antibiotics. This is an extremely important feature of Enterogermina as it allows you to take it even while you are being treated with antibiotics, so as to prevent intestinal flora imbalances caused by the antibiotics themselves (penicillins, cephalosporins, tetracyclines, macrolides, aminoglycosides, novobiocin, chloramphenicol, thiamphenicol, lincomycin, isoniazide, cycloserine, rifampicin, nalidixic acid and pipemidic acid).

**Presentation**

**Mini bottles**

Enterogermina is liquid and comes in two boxes of 10 or 20 bottles each containing 5 millilitres.

**Capsules**

Enterogermina takes the form of capsules and comes in two boxes each containing 12 or 24 capsules.

**What it is**

Enterogermina is an anti-microbial agent for the intestine, that is, it contains anti-diarrhoic microorganisms, so it is a drug for treating intestinal bacterial flora disorders.

**Marketing Authorization Holder**

sanofi-aventis S.p.A. – Viale L. Bodio, 37/b - IT - 20158 Milan (Italy)

**Manufacturer and Final Controller**

**Mini bottles**

Production plants:
- Laboratoire Unither – Zi De la Guérie – F - 50211 Coutances Cedex (France)
- sanofi-aventis S.p.A. – Viale Europa, 11 – IT - 21040 Origgio (Va) (Italy)

**Capsules**

Production plant: Doppel Farmaceutici S.r.l. - Via Volturno, 48 - IT - 20089 Quinto de' Stampi MI (Italy)
What it is for
Enterogermina is used to cure and prevent intestinal bacterial flora disorders. Enterogermina restores the intestinal flora balance upset during treatment with antibiotics or chemotherapeutic products, helping to correct consequent dysvitaminosis conditions (that is, anomalous vitamin production and assimilation). Enterogermina 2 thousand million/5 ml oral suspension can also be used in breast-feeding infants to cure acute and chronic gastrointestinal disorders caused by intoxication or bacterial flora disorders with anomalous production and assimilation of vitamins.

When it should not be used
Hypersensitivity to the active ingredient or any of the excipients.

What to do during pregnancy and lactation
Enterogermina may be used during pregnancy and lactation.

Precautions for use
During treatment with antibiotics, we recommend Enterogermina be administered during the interval between antibiotic administrations.

What drugs or food may modify the effect of the medicinal product
No drugs or food are known to modify the effect of Enterogermina. If you are taking other medicinal products, consult your doctor or pharmacist.

It is important to know that
If corpuscles, or tiny particles, can be seen in the bottles of Enterogermina, this does not mean that the product has deteriorated as these particles are simply clumps of Bacillus clausii spores.

Health education notes
The bacterial flora of the intestines constitutes a defensive barrier against harmful bacteria. Its balance can be upset by intestinal infections, intoxications, food disorders, unbalanced diet, use of antibiotics. The symptoms of this imbalance are diarrhoea, abdominal pain, surplus air in the intestine.

How to use this product

How much
Adults: 2 - 3 bottles a day or 2 - 3 capsules a day
Children: 1 - 2 bottles a day or 1 - 2 capsules a day
Breast-feeding infants: 1 - 2 bottles a day
Warning: do not exceed the doses indicated without consulting a doctor.

When and how long for
Take Enterogermina at regular intervals during the day. Consult a doctor if the disorder occurs repeatedly or you have noticed any recent change in its characteristics.
Warning: only use for short periods of treatment.

How
Bottles
Shake before use. To open the bottle, unscrew and remove the top of the cap. Take the contents as it is or dilute it in water or other drink (e.g. milk, tea, orangeade). Once open, the drug should be taken within a short time to avoid contaminating the suspension.

Capsules
Swallow the capsules with a little water or other drink. Especially in young children, use of the oral suspension is recommended as they may have trouble swallowing the rigid capsules.
What to do if you have taken more than the indicated dose of the product
Excessive doses of Enterogermina do not generally cause undesired effects. Do not exceed the recommended doses.

What to do if you have forgotten to take one or more doses
There are no particular problems. It should however be borne in mind that the therapeutic effect is favoured if the product is taken regularly.

Effects of discontinuing treatment
No particular effects have been reported, apart from failure to obtain the therapeutic effect.

Undesired effects
No undesired effects have been reported.
In any case, the onset of any undesired effects not described in the package leaflet should be promptly reported to your doctor or pharmacist.
Ask for and fill in the undesired effect report form available at your chemist’s (form B).

Shelf life and storage
Enterogermina bottles have a shelf life of 2 years.
Enterogermina capsules have a shelf life of 3 years.
Warning: do not use the drug after the expiry date printed on the box. The expiry date indicated refers to the product in its undamaged package, correctly stored.
Store at a temperature of no more than 30° C.

KEEP THE PRODUCT OUT OF THE REACH OF CHILDREN

It is important always to have the information about the product close at hand, so keep the box and the package leaflet in a safe place.

Latest revision of the package leaflet by the Italian Drug Agency: December 2008