For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

This package insert is continually updated: Please read carefully before using a new pack

Spores of polyantibiotic-resistant *Bacillus clausii*
ENTEROGERMINA®
2 billion/capsule

COMPOSITION
One hard gelatin capsule contains spores of polyantibiotic-resistant *Bacillus clausii* - 2 billion (strains: O/C, N/R, SIN and T)
Approved colour used in capsule shell: Titanium dioxide I.P.

PHARMACEUTICAL FORM
Capsules

CLINICAL PARTICULARS
Therapeutic indications
For the treatment of alterations in the intestinal bacterial flora.

Posology and method of administration
Adults*:* 2-3 capsules per day
Children: 1-2 capsules per day
Swallow with a sip of water or some other beverage like sweetened water, milk, tea or orange juice.

Enterogermina® is also available in mini bottles containing oral suspension. For young children who have difficulty in swallowing the hard capsules, it is better to use the oral suspension.

Enterogermina capsules and mini bottles containing oral suspension are for oral use only. Do not inject or administer in any other way (see Section Special warnings and special precautions for use). Do not use for more than 30 days.

Contraindications
Ascertained hypersensitivity towards the components of the product.

Special warnings and special precautions for use

Special warnings
This medicine is for oral use only. Do not inject or administer in any other way. Severe anaphylactic reactions, such as anaphylactic shock, have occurred with incorrect route of administration.

There have been reports of bacteremia, septicemia or sepsis in patients taking Bacillus clausii who are immunocompromised or are hospitalized due to a serious illness. ENTEROGERMINA® should be used in these patients only if the potential benefits outweigh the potential risks.

Precautions for use
During antibiotic therapy, the product should be administered in the interval between one dose of antibiotic and the next. Contact your doctor if the condition worsen after 2-3 days of usage.
Keep out of the reach of children.

Interactions with other medicinal products and other forms of interaction.
There are no known medicinal interactions subsequent to the concomitant administration of other drugs.

Pregnancy and lactation
Limited data are available on the use of probiotics including Enterogermina® in pregnant women. However, no conclusions can be drawn regarding whether or not Enterogermina® is safe for use during pregnancy. Enterogermina® should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus.

There are limited available data on the presence of Enterogermina® in human milk, milk production, or the effects on the breastfed infant. However, no conclusions can be drawn regarding whether or not Enterogermina® is safe for use during breastfeeding. Enterogermina® should be used during breastfeeding only if the potential benefits to the mother outweigh the potential risks, including those to the breastfed child.

Effects on ability to drive and use machines
The drug does not interfere with the ability to drive or use machinery.

Undesirable effects
During post marketing experience, hypersensitivity reactions, including rash urticaria and angioedema have been reported.

Bacteremia, septicemia or sepsis in immunocompromised patients or those hospitalized due to a serious illness.

Overdose
Up to the present time no clinical manifestations of overdose have been reported.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties
ENTEROGERMINA® is a preparation of *Bacillus clausii* spores, normal inhabitants of the intestine, with no pathogenic properties.

Administered orally*, Bacillus clausii* spores, due to their high resistance to both chemical and physical agents, cross the barrier of the acid gastric juices reaching, unharmed, the intestinal tract where they are transformed into metabolically active vegetative cells. The administration of ENTEROGERMINA® contributes to the recovery of the intestinal microbial flora altered during the course of intestinal microbial imbalance of diverse origin, due to the action of the *Bacillus clausii*. Furthermore, since the *Bacillus clausii* is capable of producing various vitamins, in particular group B vitamins, it contributes to correcting the dysvitaminosis caused by antibiotics and chemotherapeutic agents in general. ENTEROGERMINA® makes it possible to obtain an aspecific antigenic and antitoxic action, closely connected with the metabolic action of the *B. clausii.*

In addition, the high degree of heterologous resistance to the antibiotics, induced artificially, provides for the creation of the therapeutic basis for preventing the alteration of the intestinal microbial flora, following the selective action of antibiotics, especially the broad spectrum ones, or to re-establish its balance.

Because of this antibiotic-resistance, ENTEROGERMINA® can be administered in the interval between two doses of antibiotic. The antibiotic-resistance refers to: Penicillin, the Cephalosporins, Tetracyclines, Macrolides, Aminoglycosides, Novobiocin, Chloramphenicol, Thiamphenicol, Lincomycin, Isoniazid, Cycloserine, Rifampicin, Nalidixic acid and Pipemidic acid.

PHARMACEUTICAL PARTICULARS

Incompatibilities
There is no known incompatibility.

Storage
Store at a temperature not exceeding 25°C.

Manufactured by:
Sanofi Healthcare India Private Limited
At Khasra No. 141 to 143 & 145, Mohabewala Industrial Area, Dehradun – 248110 (Uttarakhand).

Bulk capsules manufactured by Sanofi S.R.L.,Viale Europa,11 - 21040 Origgio (VA) – Italy

Importer: Sanofi Healthcare India Pvt. Ltd., Bldg No. D6, Gala No. 9, Shree Arihant complex, Retibunder Road, Kalher Bhiwandi, Thane - 421302.

Source:
1. Bacillus clausii CCSI v3 LRC dated 12 Mar 2020
2. SmPC dated January 2012

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