

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

Approved colour used in capsule shell: Titanium dioxide IP

#### **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.

##### **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**

There are no contraindications regarding the use of the product during pregnancy and lactation.

##### **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.

#### **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-Synthelabo (India) Private Limited  
at Khasra No. 141 to 143 & 145,  
Mohabewala Industrial Area,  
Dehradun – 248110 (Uttarakhand).

Bulk capsules manufactured by Sanofi S.p.A , Origgio (VA), Italy

Importer: Sanofi-Synthelabo (India) Private Ltd., City Link Warehousing Complex, Bhiwandi-421302.

#### **Source :**

1. **GLU\_Bacillus Clausii\_May 2015**
2. **SmPC dated January 2012**

**Updated : -June 2018**