

Spores of Polyantibiotic – resistant *Bacillus clausii*

ENTEROGERMINA®

2 billion/capsule

Abridged Prescribing Information

COMPOSITION: One hard 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.

THERAPEUTIC INDICATIONS: For the treatment of alterations in the intestinal bacterial flora.

DOSAGE 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. Do not use for more than 30 days.

SAFETY-RELATED INFORMATION

CONTRAINDICATIONS: Ascertained hypersensitivity towards the components of the product.

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

PREGNANCY AND LACTATION: Enterogermina® should be used during pregnancy and breastfeeding only if the potential benefits to the mother outweigh the potential risks, including those to the fetus or breastfed child.

ADVERSE REACTIONS: 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.

For full prescribing information, please write to : Sanofi Healthcare India Private Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Source:

1. *Bacillus clausii* CCSI v3 LRC dated 12th March 2020

2. SmPC dated January 2012

Updated: Dec 2021