

**Abridged Prescribing Information**

**Spores of Polyantibiotic – resistant *Bacillus clausii***

**ENTEROGERMINA®**

2 billion/capsule

**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 other drinks. Do not use for more than 30 days.

**SAFETY-RELATED INFORMATION**

**CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients

**WARNINGS& PRECAUTIONS:** 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. During treatment with antibiotics, it is recommended that the preparation be administered between antibiotic doses.

**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.

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 12<sup>th</sup> March 2020
2. Italian SmPC dated February 2021

**Updated:** June 2023