

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

Spores of Polyantibiotic-resistant *Bacillus clausii*

ENTEROGERMINA®

2 billion / 5 mL oral suspension

Abridged Prescribing Information

COMPOSITION: One 5mL mini bottle contains spores of polyantibiotic-resistant *Bacillus clausii* - 2 billion (strains: OC, NR, SIN and T)

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

DOSAGE AND METHOD OF ADMINISTRATION: Adults:2-3 mini bottles per day; Children:1-2 mini bottles per day; Infants:1-2 mini bottles per day, unless prescribed otherwise by the doctor. Administration at regular intervals, Take the mini bottle as it is or dilute it in water or other beverages (e.g., milk, tea, orange juice) This medicinal product is for oral use only. Do not inject or administer in any other way.

SAFETY-RELATED INFORMATION

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

WARNINGS & PRECAUTIONS: Possible presence of corpuscles visible in the mini bottles of Enterogermina® is due to aggregates of *Bacillus clausii* spores. Shake the mini bottle before use.

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 12th March 2020
2. Italian SmPC dated February 2021

Updated: November 2022