

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

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.

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: No contraindications.

ADVERSE REACTIONS : During post marketing experience, hypersensitivity reactions, including rash urticaria and angioedema, have been reported.

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

Source :

1. GLU_*Bacillus Clausii*_May 2015
2. SmPC dated January 2012

Updated : June 2018