Enterogermina®

2 billion/ 5 ml, oral suspension
Spores of poly-antibiotic resistant *Bacillus clausii*

SANOFI

QUALITATIVE AND QUANTITATIVE COMPOSITION
Oral suspension: Spores of poly-antibiotic resistant *Bacillus clausii* 2 billion.
For a full list see list of Excipients.

PRODUCT DESCRIPTION
Oral suspension: Whitish, opalescent, liquid.

CLINICAL PARTICULARS
Therapeutic indications
Treatment and prophylaxis of intestinal dysmicrobism and subsequent endogenous dysvitaminosis. Therapy for aiding the recovery of the intestinal microbial flora, altered during the course of treatment with antibiotics or chemotherapeutic agents. Acute and chronic gastrointestinal disorders in breastfeeding infants, attributable to intoxication or intestinal dysmicrobism and dysvitaminosis.

Posology and method of administration
Adults: 2-3 minibottles per day; children: 1-2 minibottles per day; breastfeeding infants: 1-2 minibottles per day.
Minibottles: administration at regular intervals (3-4 hours), taking the contents of the minibottles as it is or diluting it in water or other drink (e.g. milk, tea, orange juice).
This medicine is for **ORAL** use only. **DO NOT inject** or administer in any other way.

Contraindications
Hypersensitivity to the active ingredient or any of the excipients.

Special warnings and precautions for use
Special warnings: The possible presence of corpuscles visible in the minibottles of ENTEROGERMINA is due to aggregates of *Bacillus clausii* spores and does not, therefore, indicate that the product has undergone any changes. Shake the minibottle before use.
Precautions for use: During antibiotic therapy, the product should be administered in the interval between one dose of antibiotic and the next.
This medicinal product is for oral use only. Do not inject or administer in any other way. Incorrect use of the medicinal product has caused severe anaphylactic reactions such as anaphylactic shock.

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 while breast-feeding.

Effects on ability to drive and use machines
The drug does not interfere with the ability to drive or use machines.

Undesired effects
Skin and subcutaneous tissue disorders:
Unknown: hypersensitive reactions, including rash, hives and angioedema.

Overdose
Up to the present time no clinical manifestations of overdose have been reported.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic category: A07FA – anti-diarrheal microorganisms
ENTEROGERMINA is a product consisting of a suspension of *Bacillus clausii* spores, which occur naturally in the intestine and are non-pathogenic. When administered orally, the elevated resistance of *Bacillus clausii* spores to both chemical and physical agents allows them to cross the barrier of gastric juice, and to be unharmed when they reach the intestinal tract where they are transformed into metabolically active vegetative cells.
Because of the activity of *Bacillus clausii*, the administration of ENTEROGERMINA contributes to the restoration of intestinal microbial flora altered by dysmicrobism of varying origins. As *Bacillus clausii* is also capable of producing various vitamins, especially B vitamins, ENTEROGERMINA aids in correcting avitaminosis due to antibiotics and chemotherapy in general. ENTEROGERMINA produces an aspecific antigenic and antitoxic effect, closely connected with the metabolic action of *Bacillus clausii*.
The high level of artificially induced heterologous resistance to antibiotics creates the therapeutic conditions for preventing the alteration of microbial intestinal flora by the selective action of antibiotics, particularly broad-spectrum antibiotics, or for restoring them.
Due to its antibiotic resistance, ENTEROGERMINA may be administered between two subsequent administrations of antibiotics.
Antibiotic resistance refers to: penicillins, if not in combination with beta-lactamase inhibitors, cephalosporins (partial resistance in most cases), tetracyclines, macrolides, aminoglycosides (except for gentamicin and amikacin), chloramphenicol, thiamphenicol, lincomycin, clindamycin, isoniazid, cycloserine, novobiocin, rifampicin, nalidixic acid and pipemidic acid (intermediate resistance), and metronidazole.

Pharmacokenetic properties
Absorption and elimination
Enterogermina® is not absorbed from the gastrointestinal tract. In animals, low numbers of *B. clausii* cells were found in mesenteric

ganglia after administration of large doses of Enterogermina® but no cells were found in the blood or spleen.
No intrinsic factor (age, sex, race, genetic polymorphism, renal or hepatic impairment) is likely to influence the fate of Enterogermina® in the organism.

PHARMACEUTICAL PARTICULARS
List of excipients
Oral suspension: Purified water.

Shelf-life
As indicated on the outer package.

Special precautions for storage
Store at a temperature no higher than 30°C.

Nature and contents of container
Cardboard box containing 10 or 20 minibottles which made of LDPE.
Not all pack size are marketed.

Special precautions for disposal and handling
Oral suspension: shake the minibottle before use.

MANUFACTURER
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