Enterogermina®

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ENTEROGERMINA 2 billion / 5 ml oral suspension
ENTEROGERMINA 2 billion rigid capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial contains:
Active ingredient:
2 billion polyantibiotic-resistant *Bacillus clausii* spores (strains SIN, O/C, T, N/R)
One capsule contains:
Active ingredient:
2 billion polyantibiotic-resistant *Bacillus clausii* spores (strains SIN, O/C, T, N/R)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
Rigid capsules.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Treatment and prevention of intestinal dysmicrobism and subsequent endogenous avitaminosis.
Coadjuvant treatment to restore intestinal microbial flora altered during treatment with antibiotics or chemotherapy.
Acute and chronic gastrointestinal disorders in infants, attributable to poisoning or intestinal dysmicrobism and avitaminosis.

4.2. Dosage and method of administration

Adults: 2-3 vials per day or 2-3 capsules per day.
Children: 1-2 vials per day or 1-2 capsules per day.
Infants: 1-2 vials per day.
Vials: administration at regular intervals. Take the vial content as it is or dilute it in water or other beverages (e.g., milk, tea, orange juice).
Capsules: swallow accompanied by a sip of water or other drinks.
Particularly in younger children, if they have difficulty swallowing rigid capsules, use oral suspension instead.
This medication is for oral use only. Do not inject, or administer in any other way (see section 4.4).

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

Special warnings
Any presence of visible corpuscles in the vials of ENTEROGERMINA is due to aggregates of *Bacillus clausii* spores; it does not therefore suggest that the product has been altered.
Shake the vial before use.

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.

Precautions for use
During treatment with antibiotics, it is recommended that the preparation be administered between antibiotic administrations.

4.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6. Fertility, pregnancy and lactation

There are no contraindications for use of the preparation during pregnancy or lactation.

4.7. Effects on ability to drive and use machines

Enterogermina has no influence on the ability to drive and use machines.

4.8. Undesirable effects

Skin and subcutaneous tissue disorders:
unknown: hypersensitive reactions, including rash, hives and angioedema.

Infections and infestations:
bacteraemia (in immunocompromised patients)

Reporting of suspected adverse reactions.
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the risk/benefit ratio of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system at http://www.agenziafarmaco.gov.it/content/come-segnalare-una-sospetta-reazione-avversa

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4.9. Overdose
No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic category: antidiarrhoeal microorganisms
ATC Code: A07FA
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.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Vials: Purified water.
Capsules: Heavy kaolin, Microcrystalline cellulose, Magnesium stearate, Gelatine, Titanium dioxide (E171), Purified water.

6.2. Incompatibilities
None.

6.3. Shelf life
Vials
2 years.
After opening the vial, consume the preparation within a short time to avoid any pollution of the suspension.
Capsules
3 years.

6.4. Special precautions for storage
Store below 30°C.

6.5. Nature and contents of container
Vials: lithographed cardboard box containing 10 or 20 vials.
Capsules: lithographed cardboard box containing 1 or 2 blister packs, each with 12 capsules.

6.6. Special precautions for disposal and other handling
Vials: shake the vial before use.

7. MARKETING AUTHORISATION HOLDER
Sanofi S.p.A. – Viale L. Bodio, 37/b – IT-20158 Milano (Italy)

8. MARKETING AUTHORISATION NUMBERS
AIC 013046038 "ENTEROGERMINA 2 billion / 5 ml oral suspension" Pack of 10 vials of 5ml

AIC 013046040 "ENTEROGERMINA 2 billion / 5 ml oral suspension" Pack of 20 vials of 5ml

AIC 013046053 "ENTEROGERMINA 2 billion rigid capsules" Pack of 12 capsules

AIC 013046065 "ENTEROGERMINA 2 billion rigid capsules" Pack of 24 capsules

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
First authorisation date: 14 November 2001
Date of latest renewal: 30 July 2008

10. DATE OF REVISION OF THE TEXT
October 2018