SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ENTEROGERMINA 2 thousand million / 5 ml oral suspension
ENTEROGERMINA 2 thousand million hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One minibottle contains:
Active ingredient:
Spores of polyantibiotic-resistant *Bacillus clausii* 2 thousand million
One hard capsule contains:
Active ingredient:
Spores of polyantibiotic-resistant *Bacillus clausii* 2 thousand million

For a full list of excipients, see paragraph 6.1

3. PHARMACEUTICAL FORM

Oral suspension.
Hard capsules.

4. CLINICAL PARTICULARS

4.1 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.

4.2 Posology and method of administration

Adults: 2-3 minibottles per day or 2-3 capsules per day; children: 1-2 minibottles per day or 1-2 capsules per day; breastfeeding infants: 1-2 minibottles per day.
Minibottles: administration at regular intervals (3-4 hours), taking the contents of the minibottle as it is or diluting it in water or other drink (e.g. milk, tea, orange juice).
Capsules: swallow with a sip of water or some other beverage.
Especially in the case of very young children, in the event of difficulty in swallowing the hard capsules, it is better to use the oral suspension.
This medicine is for oral use only. Do not inject or administer in any other way.

4.3 Contraindications

Hypersensitivity to the active ingredient or any of the excipients.

4.4 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.

4.5 Interactions with other medicinal products and other forms of interaction
There are no known medicinal interactions subsequent to the concomitant administration of other drugs.

4.6 Pregnancy and lactation
There are no contraindications regarding the use of the product during pregnancy and while breast-feeding.

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

4.8 Undesired effects
In post-marketing experience cases of hypersensitivity reactions including rash and urticaria have been reported.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic category: A07FA49 – anti-diarrhoeal microorganisms
ENTEROGERMINA is a preparation consisting of a suspension of spores of *Bacillus clausii*, a normal inhabitant of the intestine, with no pathogenic powers.
Administered orally, *Bacillus clausii* spores, thanks to their high resistance to both chemical and physical agents, cross the barrier of the acid gastric juices reaching, unharmed, the intestinal tract where they are transformed into metabolically active vegetative cells.
The administration of ENTEROGERMINA contributes to the recovery of the intestinal microbial flora altered during the course of dysmicrobisms of diverse origin, thanks to the action of the *Bacillus clausii.* Furthermore, since the *Bacillus clausii* is capable of producing various vitamins, in particular group B vitamins, ENTEROGERMINA contributes to correcting the dysvitaminosis caused by antibiotics and chemotherapeutic agents in general. ENTEROGERMINA makes it possible to obtain an aspecific antigenic and antitoxic action, closely connected with the metabolic action of the clausii.
In addition, the high degree of heterologous resistance to the antibiotics, induced artificially, provides for the creation of the therapeutic basis for preventing the alteration of the intestinal microbial flora, following the selective action of antibiotics, especially the broad spectrum antibiotics, or to re-establish its balance.
Because of this antibiotic-resistance, ENTEROGERMINA can be administered in the interval between two doses of antibiotic. The antibiotic-resistance refers to: penicillins,

cephalosporins, tetracyclines, macrolides, aminoglycosides, novobiocin, chloramphenicol, thiamphenicol, lincomycin, isoniazid, cycloserine, rifampicin, nalidixic acid and pipemidic acid.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Minibottles: Purified water.
Capsules: Kaolin, Microcrystalline cellulose, Magnesium stearate, Gelatin, Titanium dioxide (E171), Purified water.

6.2 Incompatibilities

There are no known incompatibilities.

6.3 Shelf-life

Minibottles
2 years.
Once open, the drug should be taken within a short time to avoid contaminating the suspension.
Capsules
3 years.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

Minibottles: lithographed cardboard box containing 10 or 20 minibottles.
Capsules: lithographed cardboard box containing 1 or 2 blister strips of 12 capsules each.

6.6 Special precautions for disposal and handling

Minibottles: shake the minibottle before use.

7. MARKETING AUTHORISATION HOLDER

sanofi-aventis S.p.A. – Viale L. Bodio, 37/b – IT-20158 Milan (Italy)

8. MARKETING AUTHORISATION NUMBERS

Pack of 10 minibottles	M.A. 013046038
Pack of 20 minibottles	M.A. 013046040
Pack of 12 capsules	M.A. 013046053
Pack of 24 capsules	M.A. 013046065

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization:

Oral suspension	14 November 2001
Capsules	9 December 2004

Date of latest renewal: 30 July 2008

10. DATE OF REVISION OF THE TEXT

February 2010