SANOFI **Regional Packaging Unit (RPU)**

GENERAL

| | |
|---|---|
| Code | : ERF4sLt10sPH0316v1 |
| Update | : 02.03.2016 - ver 1 |
| Local Code SCM | : 000000 |
| Current item code | : 000000 |
| Product/Item type | : Erceflora 4B bottle - Leaflet |
| Pack Size | |
| Box of | : 10s |
| Blister | : 0 x 00 |
| Country | : PH |
| Languages | : English |
| Market Barcode | : 000000000000 |
| Artwork by | : Analyn NOVILLAS |
| Revised by | : Xxxxxxx |
| Plant | : Sanofi Origgio, Italy |

TECHNICAL

Format : **185 x 155 mm** (text area - based on size from plant)/ **370 x 155 mm**

Plant barcode :

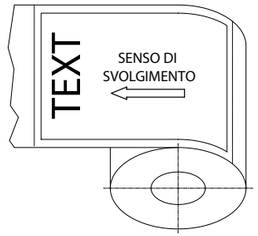
Colour(s): 1

■ Pantone Reflex Blue C

Font(s) : Ocean San Pro San

Size : 7.5 pts (mini)

Technical Plans: xxxx




124,7 mm

75 mm

# *Bacillus clausii*
# *Erceflora*

4 billion/ 5 mL Oral suspension

Antidiarrheal of Microbial Origin

SANOFI

**Formulation**
Each 5 mL suspension contains:
Spores of Polyantibiotic-resistant *Bacillus clausii* ……..…… 4 billion

Excipient: purified water q.s.

**Therapeutic indications**
Therapy and prevention of intestinal dismicrobism 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 dismicrobism and avitaminosis.

**Dosage and Method of Administration**
Adults: 1 vial per day.
Breast-feeding infants and children: 1 vial per day.
Take the vial content as-is or dilute it in water or other beverages (e.g. milk, tea, orange juice).

This medication is for oral use only. Do not inject, or administer in any other way.

Shake well before use.

**Contraindications**
Hypersensitivity to the active substance or to any of the excipients

**Special warnings and precautions for use**
*Special warnings*
Any presence of visible corpuscles in the bottles of *Bacillus clausii (Erceflora)* is due to aggregates of *Bacillus clausii* spores; does not therefore suggest that the product has been altered. Shake the vial before use.

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

**Interactions with other medicinal products and other forms of interaction**
No interaction studies have been performed.

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

**Effects on ability to drive and use machines**
*Bacillus clausii (Erceflora)* has no or negligible influence on the ability to drive and use machines.

**Side effects**
During product marketing, cases of hypersensitive reactions were reported, including rashes and hives.

**Overdose**
No cases of overdose have been reported.

**Pharmacological Properties**
*Pharmacodynamic Properties*
Pharmacotherapeutic group: A07FA – antidiarrhoeal microorganisms

*Bacillus clausii (Erceflora)* 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 *Bacillus clausii (Erceflora)* contributes to the restoration of intestinal microbial flora altered by dismicrobism of varying origins. As *Bacillus clausii* is also capable of producing various vitamins, especially B vitamins, *Bacillus clausii (Erceflora)* aids in correcting avitaminosis due to antibiotics and chemotherapy in general. *Bacillus clausii (Erceflora)* 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, *Bacillus clausii (Erceflora)* may be administered between two successive 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.

**Incompatibilities**
There is no known incompatibility.

**Shelf life**
Stability in unopened container: 2 years
After opening the vial, the preparation should be administered immediately to avoid contaminating the suspension.

**Storage**
Store at a temperature below 30°C.

**Availability**
Box containing 10 bottles x 5 mL

**Reporting of Side Effects or any Suspected Adverse Event**
For suspected adverse drug reactions, report to **www.fda.gov.ph** and **CHCPV@sanofi.com**. Patients should seek medical attention immediately at the first sign of any adverse drug reaction.

By reporting side effects, you can help provide more information on the safety of this product.

**Manufactured by**
Opella Healthcare Italy S.r.l.
Viale Europa, 11 - 21040 Origgio (VA) Italy

**Imported by**
Opella Healthcare Philippines, Inc.
21st, 22nd and 23rd Floors, One World Place,
32nd St., Bonifacio Global City, Taguig City

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SmPC October 2014
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