

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Infloran hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One capsule contains:

Active substances:

- | | |
|---|----------------------------|
| - Viable lyophilised <i>Bifidobacterium bifidum</i> | no less than 1,000 million |
| - Viable lyophilised <i>Lactobacillus acidophilus</i> | no less than 1,000 million |

Excipients with known effect: Sucrose, lactose monohydrate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis.

Prevention of gastrointestinal dismicrobism syndromes.

Treatment.

Diarrhoeic and dyspeptic syndromes due to altered bacterial flora (diarrhoea, non-specific enteritis in adults and infants, colitis). Dismicrobism due to antibiotics. Digestive disorders in formula-fed infants. Adjuvant in the elimination of pathogenic, chemoantibiotic-resistant enterobacteria.

4.2 Posology and method of administration

Posology

One capsule three times daily.

Method of administration

For both children and adults swallow with some non warm liquid, before meals.

Pediatric population

For infants pour the content of the capsule into a little non warm liquid or sugared water.

Do not exceed the recommended doses.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Do not use for prolonged treatments. After a short period of treatment without significant results, ask the doctor. There might be batch-related differences in the colour of the lyophilised content due to the excipients contained in the preparation.

The medicinal product contains **lactose**. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

The medicinal product contains **sucrose**. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Not reported.

4.6 Fertility, pregnancy and lactation

Infloran can be administered during pregnancy and breast-feeding.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

No undesirable effects have been reported at the recommended doses.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system at the following web-address: <http://www.agenziafarmaco.gov.it/it/responsabili>.

4.9 Overdose

No overdose reactions have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotheapeutic group: lactic acid producing organisms, combinations ATC: A07FA51

Mechanism of action

Eubiotic saprophytes of the human intestine. They balance and restore intestinal bacterial flora, inhibit colonisation by pathogens through antibiosis mechanisms, and are effective against intestinal dismicrobism caused by chemoantibiotics.

5.2 Pharmacokinetic properties

Being components of the natural intestinal flora, they rapidly colonise, they activate physiological functions of intestinal flora and they survive in the bowel.

5.3 Preclinical safety data

No data from studies on animal models are available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, sodium citrate, magnesium stearate, dipotassium phosphate, lactose monohydrate

Shell excipients

Gelatine, titanium dioxide (E171), erythrosine (E127), indigotine (E132), quinolin yellow (E104).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).

Store in the original package to protect from light.

6.5 Nature and contents of container

Infloran is available in a pack of 20 hard capsules in PVC/PVDC and Aluminum blister.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratorio Farmaceutico S.I.T. S.r.l. - Via Cavour 70 – 27035 Mede (PV).

8. MARKETING AUTHORISATION NUMBER

024037018

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 October 1979

Date of last renewal: 1 June 2010.

10. DATE OF REVISION OF THE TEXT

28/06/2015