IDENTIFICATION OF MEDICINAL PRODUCT

Name: BIOFLOR® 250 mg, powder for oral suspension

Composition

Saccharomyces boulardii CNCM I-745®: 250 mg

Excipients: lactose monohydrate, fructose, colloidal anhydrous silica, tutti-frutti flavour (containing sorbitol).

Properties

Bioflor is a probiotic. Its active ingredient consists of living microorganisms.

INDICATIONS

Helps to reduce the risk of antibiotic-associated diarrhea in adults.

WARNING AND PRECAUTIONS

BIOFLOR® 250 mg contains living cells. This drug should therefore not be mixed with very hot (over 50°C), iced or alcoholic drinks or food.

It is advisable not to open sachets in the surroundings of patients with a central venous catheter, to avoid any colonization, especially hand-borne, of the catheter. There have been reports in patients with a central venous catheter, even not treated with *S. boulardii* CNCM I-745®, of very rare cases of fungemia (penetration of blood by yeast) and sepsis, most often resulting in pyrexia and blood cultures positive for *Saccharomyces*. The outcome in all these cases has been satisfactory after administration of antifungal treatment and, when necessary, removal of the catheter.

Discontinue use and consult a health care practitioner if symptoms of digestive upset (e.g. diarrhoea) occur, worsen, or persist beyond 3 days.

Contra-indications

• Hypersensitivity to one of the components

• Allergy to yeasts

• Patients experiencing nausea, fever, vomiting, bloody diarrhoea or severe abdominal pain

• Immunocompromised or hospitalized patients (due to serious illness or altered/weakened immune system e.g. AIDS, lymphoma, patient undergoing long-term corticosteroid treatment)

• Patients with central venous catheter

BIOFLOR® 250 mg, powder for oral suspension contains lactose monohydrate.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine.

BIOFLOR® 250 mg, powder for oral suspension contains fructose.
This medicine contains 471.90 mg fructose in each sachet. In case of frequent use or over a long period of time (e.g. for two weeks or longer), fructose can damage teeth. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with

hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

BIOFLOR® 250 mg, powder for oral suspension contains sorbitol.
This medicine contains 0.10 mg sorbitol in each sachet.

Drug interactions and other forms of interaction

Due to the fungal nature of *Saccharomyces boulardii* CNCM I-745®, do not use this medicine at the same time as an antifungal agent (medicine active against fungus infections).

Pregnancy and lactation

It is advisable not to use this medicine during pregnancy.

If you discover that you are pregnant during the treatment, consult your physician.

As a general rule, during pregnancy or lactation it is advisable to ask your physician or your pharmacist for advice before taking any medicine.

HOW TO USE THIS MEDICINE

Dosage

1 to 2 sachets given once or twice daily up to a maximum of 2 weeks.

Method and route of administration

Pour the contents of the sachets in a little amount of water or sweetened beverage, mix, and drink. It should not be poured or mixes with very cold or very hot liquids nor alcoholic drinks.

Overdose

No case reported. If you have taken more Bioflor than you should, contact your pharmacist or your physician for advice.

If symptoms persist, please consult your healthcare practitioner.

SIDE EFFECTS

Very rare side effects:

- Penetration of yeast into blood (fungemia),
- Allergic reactions: pruritus, wheal formation (urticaria), skin rash, either locally restricted affecting the entire body (local or generalized exanthema), swelling of the connective tissue of the face (angioedema),
- Anaphylactic reaction or even shock

Frequency not known:

Serious blood infection (sepsis) in critically ill or immunocompromised patients, flatulence, constipation and headache.

STORAGE

Do not exceed the expiry date shown on the outer packaging.

Special storage precautions

Store away from humidity at a temperature below 30°C.

DATE OF REVIEW OF PACKAGE INFORMATION LEAFLET:

March 2021

Form and presentation

Sachet: box of 10 sachets and 200 sachets.

Name and address of the MA holder

BIOCODEX - 7 avenue Gallieni - 94250 GENTILLY, FRANCE

Name and address of the Manufacturer

BIOCODEX - 1 avenue Blaise Pascal - 60000 BEAUVAIS, FRANCE

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