

BIOFLOR[®] CAPSULES/SACHETS

Saccharomyces boulardii CNCM I-745 (250mg)

What is in this leaflet

1. What *BIOFLOR*[®] is used for
2. How *BIOFLOR*[®] works
3. Before you use *BIOFLOR*[®]
4. While you are using it
5. Side effects
6. Storage and Disposal of *BIOFLOR*[®]
7. Product Description
8. Manufacturer and Product Registration Holder
9. Date of revision

What *BIOFLOR*[®] is used for
BIOFLOR[®] is indicated for acute diarrhoea in infants, children and adults; prevention of antibiotic-associated diarrhoea in children and adults; prevention of recurrence of *Clostridium difficile* in adults and prevention of diarrhoea during continuous enteral tube feeding in adults.

Ask your doctor or pharmacist if you are not sure why you need to take *BIOFLOR*[®].

How *BIOFLOR*[®] works

Saccharomyces boulardii CNCM I-745 is an intestinal replacement flora (live probiotic yeast) which acts as antidiarrhoeal microorganisms in the digestive tract. *Saccharomyces boulardii* CNCM I-745 protects the digestive tract against pathogens, improves digestion and restore normal flora.

Before you use *BIOFLOR*[®]

- When you must not use it

Do not use if you

- Have hypersensitivity to any ingredient of *BIOFLOR*[®]
- Have yeast allergy, in particular allergy to *Saccharomyces boulardii* CNCM I-745.
- Have fructose or lactose intolerance
- Have congenital galactosemia, glucose and galactose malabsorption syndrome or lactose deficit
- Are immunocompromised (altered/weakened immune system) or have central venous catheter

Pregnancy and lactation

Do not take *BIOFLOR*[®] if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *BIOFLOR*[®] if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

BIOFLOR[®] 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.

BIOFLOR[®] sachet 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.

- Before you start to use it

Consult your doctor or pharmacist before you use *BIOFLOR*[®] if you have HIV infection or are receiving chemotherapy or irradiation.

- Taking other medicines

Tell your doctor if you are taking antifungal medicine or any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use *BIOFLOR*[®]

- How much to use

Give your infants or children 1 or 2 sachets daily.

Give your children above 6 years old, 1-2 capsules daily.

For adults, take 1-2 capsules / sachets once or twice daily.

In young children under 6 years of age, it is recommended not to swallow capsules (risk of false passage) and to give the powder for oral suspension in sachet.

Prepare the oral suspension by pouring the contents of the sachet in a glass of water or sweetened beverage, mix, and drink. The powder can also be mixed with food or poured into a baby's feeding-bottle.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Both capsules and sachets can be taken either during, before or after meals. Capsules should be swallowed with a glass of water.

- How long to use it

Always use or give *BIOFLOR*[®] to your children as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure. The maximum duration of treatment in the usual indications is 4 weeks.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Saccharomyces boulardii CNCM I-745 is not absorbed by the body, so an overdose is unlikely. If an overdose occurs, no special action is needed.

While you are using it

- Things you must do

While taking *BIOFLOR*[®], make sure to do the following:

- Drink sufficient liquid including salted or sweetened drinks to

BIOFLOR[®] CAPSULES/SACHETS*Saccharomyces boulardii* CNCM I-745 (250mg)

compensate for the loss of liquid due to the diarrhoea. Adults are recommended to drink 2 liters of water a day.

- Eat by favouring roasted meats and rice during the diarrhoea but avoid fruits, green vegetables, spicy dishes, frozen food or cold drinks. Consider reducing intake of milk and dairy products.

In case of doubt, do not hesitate to seek the advice of your doctor or your pharmacist.

You must consult your doctor immediately in the following cases:

- Do not see any improvement after 2 days of treatment.
- In case of fever, vomiting.
- In case of presence of blood or mucus in the stools.
- In case of intense thirst, dryness of tongue: these signs show the beginning of dehydration, that means an important loss of liquid due to the diarrhoea. Your doctor will decide the necessity to prescribe a rehydration.
- You become pregnant while taking this medication.

- Things you must not do

Do not take *BIOFLOR[®]* with very hot (over 50°C), iced or alcoholic drinks or food.

Do not open *BIOFLOR[®]* sachets in the surroundings of patients with a central venous catheter.

Do not take any new medicines without consulting your doctor.

Do not give *BIOFLOR[®]* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Check with your doctor or pharmacist.

Side effects

BIOFLOR[®] can cause side effects to gastrointestinal (flatulence,

constipation), skin (rash, cutaneous allergy, urticarial, pruritus), immune system (allergic response including swelling below the skin surfaces, breathing difficulties, abdominal pain, cramps, vomiting and diarrhoea) and thirst; although not everybody gets them.

Very rare side effects: Penetration of yeast into blood (fungaemia).

Unknown frequencies side effects: constipation, serious blood infection (sepsis).

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *BIOFLOR[®]*- Storage

Keep out of the reach and sight of children. Store in a cool, dry place, below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description- What it looks like

BIOFLOR[®] capsules:

Light brown powder in opaque white capsule, with characteristic odor.

BIOFLOR[®] sachets:

Paper/aluminium/polyethylene composite sachets containing a very light-brown powder with an odor of fruit.

Appearance after reconstitution/mixing with water:

liquid suspension with a milky appearance.

- Ingredients

- Active ingredient

Each capsule or sachet contains 250mg of *Saccharomyces boulardii* CNCM I-745.

- Inactive ingredients

BIOFLOR[®] capsules

- Titanium dioxide
- Lactose monohydrate
- Magnesium stearate
- Bovine capsule shell

BIOFLOR[®] sachets

- Tutti-frutti flavor (containing sorbitol)
- Lactose monohydrate
- Fructose
- Colloidal anhydrous silica

- MAL numbers:

- *BIOFLOR[®]* 250mg capsules MAL12095098X
- *BIOFLOR[®]* 250mg sachets MAL12095097X

Manufacturer

Biocodex
1, Avenue Blaise Pascal
Beauvais
60000
FRANCE

Product Registration Holder

Servier Malaysia Sdn. Bhd.
Unit No.25-02, Level 25, Imazium
No.8, Jalan SS21/37,
Damansara Uptown
47400 Petaling Jaya,
Selangor Darul Ehsan

Date of revision

15 May 2025

Serial number

NPRA(R2/2)210609/691