

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

BIOFLOR 250mg capsule ***Saccharomyces boulardii* CNCM I-745**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet

1. What BIOFLOR 250mg capsule is and what it is used for
2. What you need to know before you take BIOFLOR 250mg capsule
3. How to take BIOFLOR 250mg capsule
4. Possible side effects
5. How to store BIOFLOR 250mg capsule
6. Contents of the pack and other information

1. WHAT BIOFLOR 250mg capsule IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Anti-diarrhea. Replacement flora. (A: Digestive system and metabolism).

Therapeutic indications:

- Treatment of acute infectious diarrhoea of adults and children.
- Prevention and treatment of antibiotic-associated colitis and diarrhoea.
- Addition to vancomycin/metronidazole-treatment to prevent recurrence of *Clostridium difficile* diseases.
- Prevention of tube-feeding associated diarrhoea.
- Treatment of irritable bowel syndrome.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BIOFLOR 250mg capsule

DO NOT TAKE BIOFLOR 250mg capsule

- If you are allergic to *Saccharomyces boulardii* CNCM I-745 or any of the other ingredients of this medicine (listed in section 6).
- If you have a central venous catheter.
- In immunocompromised or hospitalised patients (due to serious illness or altered/weakened immune system) (see Warnings and precautions).

Warnings and precautions

Talk to your doctor or pharmacist before taking Bioflor 250mg capsule.

It is advisable not to open capsules in the surroundings of patients with a central venous catheter, to avoid any colonization, especially hand-borne, of the catheter. It is advisable not to open the capsules in the surroundings of critically ill or immunocompromised patients due to a risk of airborne contamination. There have been reports in patients with a central venous catheter and in critically ill or immunocompromised patients, even not treated with *S. boulardii* CNCM I-745, of very rare cases of fungemia (penetration of blood by yeast), most often resulting in pyrexia and blood cultures positive for *Saccharomyces*.

As a complement of this treatment, the following dietetic rules have to be followed:

- Rehydration by abundant, salted or sweetened drinks, in order to compensate for the loss of liquid due to the diarrhoea (the average daily ration of water in adult is 2 liters).

- To feed during the diarrhoea:

- by excluding certain supply and particularly fruits, green vegetables, spiced dishes, as well as food or frozen drinks,
- by privileging roasted meats and rice.

You must consult immediately your doctor in the following cases:

- In absence of 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 the dehydration, that means an important loss of liquid due to the diarrhea. Your doctor will decide the necessity to prescribe a rehydration which could be administered by oral or IV route.

Other medicines and BIOFLOR 250mg capsule

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Do not take this medicine at the same time as an oral antifungal agent (medicine active against fungus infections).

BIOFLOR 250mg capsules with food, drink and alcohol

This medicine contains living cells. This medicine should therefore not be mixed with very hot (over 50°C), iced or alcoholic drinks or food because it could kill the yeast.

Pregnancy and breastfeeding

The use of this medicine must generally be avoided during pregnancy.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Not relevant.

BIOFLOR 250mg capsule contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE BIOFLOR 250mg capsule

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose in adults and children above 6 years is: 1 or 2 capsule(s), taken once or twice daily.

Oral route.

The capsules must be swallowed with a glass of water.

The use of capsule in children under 6 years of age is not advisable because of possible false route absorption. It is recommended to use the powder for oral suspension in sachet.

If you take more BIOFLOR 250mg capsule than you should

In case of overdose the side effects can be worsened (allergic reactions).

If you forget to take BIOFLOR 250mg capsule

Do not take a double dose to make up for a forgotten capsule.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Rare (may affect up to 1 in 1,000 people): some cases of flatulence have been reported.

- Very rare (may affect up to 1 in 10,000 people): some cases of allergic reactions in the form of pruritus, urticaria, skin rash have been reported. Some cases of anaphylactic reaction or even shock have been reported. Penetration of yeast into blood (fungemia).
- Frequency not known: constipation, serious blood infection (sepsis).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. ADR Reporting – Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BIOFLOR 250mg capsule

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP.

The expiry date refers to the last day of that month.

Store away from humidity at a temperature below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BIOFLOR 250mg capsule contains

The active substance is: *Saccharomyces boulardii* CNCM I-745: 250.00mg

The other ingredients are: lactose, magnesium stearate. *Capsule shell:* gelatine, titanium dioxide (E171).

What BIOFLOR 250mg capsule looks like and contents of the pack

Opaque white capsules containing a light brown powder with a characteristic odor.

Box of 10 capsules, 20 capsules or 50 capsules in a glass bottle.

Marketing Authorization Holder and manufacturer

Marketing Authorization Holder

BIOCODEX

7 avenue Gallieni

Gentilly – France

Manufacturer

BIOCODEX

1 avenue Blaise Pascal

Beauvais - France

This leaflet was last revised in July 2021