PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

BIOFLOR 250mg powder for oral suspension in sachet
***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 your 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

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2. What you need to know before you take BIOFLOR 250mg powder for oral suspension in sachet
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1. WHAT BIOFLOR 250mg powder for oral suspension in sachet 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 powder for oral suspension in sachet

DO NOT TAKE BIOFLOR 250mg powder for oral suspension in sachet:
- 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 powder for oral suspension in sachet.

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. It is advisable not to open the sachets 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 the 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 powder for oral suspension in sachet
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 powder for oral suspension in sachet 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 powder for oral suspension in 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.
BIOFLOR 250mg powder for oral suspension in sachet 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.
BIOFLOR 250 mg, powder for oral suspension contains sorbitol.
This medicine contains 0.10 mg sorbitol in each sachet

3. HOW TO TAKE BIOFLOR 250mg powder for oral suspension in sachet

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 is 1 or 2 sachet(s), taken once or twice daily.

Oral route.
Pour the contents of the sachet in a little amount of water or sweetened beverage, mix, and drink. The powder can also be mixed with food. It should not be poured or mixed with very cold or very hot liquids or food nor alcoholic drinks.

If you take more BIOFLOR 250mg powder for oral suspension in sachet than you should
In case of overdose the side effects can be worsened (allergic reactions).

If you forget to take BIOFLOR 250mg powder for oral suspension in sachet
Do not take a double dose to make up for a forgotten sachet.

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 have been reported in the form of pruritus, urticaria, skin rash. Some cases of anaphylactic reaction or even shock have been reported. Swelling of the connective tissue of the face (angioedema). 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 powder for oral suspension in sachet

Keep this medicine out of the sight and reach of children.
Do not take 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 powder for oral suspension in sachet contains

The active substance is: *Saccharomyces boulardii* CNCM I-745: 250.00mg
The other ingredients are: lactose, fructose, anydrous colloidal silica, tutti frutti aroma (containing sorbitol).

What BIOFLOR 250mg powder for oral suspension in sachet looks like and contents of the pack
Paper/aluminum/polyethylene sachets containing a very light-brown powder with an odor of fruit.
Box of 10 sachets.

Marketing Authorization Holder and manufacturer

Marketing Authorization Holder
BIOCODEX
22 rue des Aqueducs
94250 Gentilly - France

Manufacturer
BIOCODEX
1 avenue Blaise Pascal
60000 Beauvais - France

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