

## **Package leaflet: Information for the patient**

### **Symbioflor 2 oral drops, suspension**

Escherichia coli bacteria

**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.

#### **What is in this leaflet**

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

#### **1. What Symbioflor 2 is and what it is used for**

Symbioflor 2 is a bacterial preparation that improves the immune system in the bowel.

Symbioflor 2 is used to regulate the body's immune system, and in gastrointestinal disorders, especially irritable bowel syndrome.

In case of persistent or severe pain, or if you find the treatment unsatisfactory, talk to your doctor.

#### **2. What you need to know before you take Symbioflor 2**

##### **Do not take Symbioflor 2:**

- if you are allergic to the bacterial concentrate containing Escherichia coli bacteria, or any of the other ingredients of this medicine (listed in section 6).
- if you have acute inflammation of the gallbladder or pancreas, or intestinal obstruction.
- during acute illnesses with fever. In this case Symbioflor 2 should be temporarily discontinued.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Symbioflor 2.

#### **Other medicines and Symbioflor 2**

There are no known interactions with other medicinal products.

### **Pregnancy and breast-feeding**

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

Although there are no known harmful effects of Symbioflor 2 on the unborn child, it should be used during pregnancy and when breast-feeding only after a careful benefit-risk assessment by the doctor.

### **Driving and using machines**

Symbioflor 2 has no or negligible influence on the ability to drive and use machines.

### **3. How to take Symbioflor 2**

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:

Adults take 10 drops 3× daily at the beginning of treatment. After one week, the dose is increased to 20 drops 3× daily.

If signs of flatulence and upper abdominal discomfort occur at the beginning of treatment, Symbioflor 2 should be taken more diluted, or the dose should be reduced or the number of drops should be increased more slowly.

Shake Symbioflor 2 well before use. This will cause slight turbidity.

Take Symbioflor 2 dissolved in a little water at mealtimes.

Symbioflor 2 contains no preservatives and is therefore susceptible to contamination in the event of improper use. This can be prevented by opening the bottle for a short time only when using this product, and by dispensing the drops carefully. Do not touch the dropper. Because of the high surface tension of Symbioflor 2, problems with starting and stopping release of the drops of solution cannot be completely avoided. Release of the drops is started by holding the bottle at an angle and tapping lightly on the bottom. The speed at which the drops come out can be changed by varying the angle at which the bottle is held.

The duration of use depends on the circumstances of the disease in question and it can be up to 6 months in chronic cases.

### **Use in children and adolescents**

Children are given 10 drops 1× daily and infants 5 drops 1× daily.

Give children and infants Symbioflor 2 dissolved in a little water with the midday meal.

### **If you take more Symbioflor 2 than you should**

No countermeasures are necessary.

### **If you forget to take Symbioflor 2**

Do not take a double dose to make up for a forgotten dose, but continue taking the dosage prescribed.

### **If you stop taking Symbioflor 2**

No special measures are indicated. If appropriate, speak to your doctor.

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.

Symbioflor 2 is generally well tolerated. The following undesirable effects may occur however:

Uncommon (may affect up to 1 in 1000 patients):

- Flatulence
- Upper abdominal discomfort
- Nausea
- Diarrhoea

Very rare (may affect up to 1 in 10,000 patients):

- Hives
- Skin rash (exanthema)
- Persistent swelling of skin and mucous membranes (angioedema)

#### **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 (see below for details). By reporting side effects you can help provide more information on the safety of this medicine.

Bundesinstitut für Arzneimittel und Medizinprodukte (German Federal Institute for Drugs and Medical Devices)

Pharmacovigilance Department

Kurt-Georg-Kiesinger Allee 3

53175 Bonn

Germany

Website: <http://www.bfarm.de/DE/Pharmakovigilanz/form/functions/formpv-node.html>

#### **5. How to store Symbioflor 2**

Do not store Symbioflor 2 above +30 °C before opening. Do not freeze.

Close the bottle tightly immediately after use and store in a refrigerator (2 °C – 8 °C).

After the bottle is opened for the first time, the contents have a shelf life of at least 3 weeks.

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

Do not use this medicine after the expiry date which is stated on the label and carton after “Exp.:”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice:  
a high degree of flocculation in the solution.

## **6. Contents of the pack and other information**

### **What Symbioflor 2 contains**

- The active substance is: Bacterial concentrate of Escherichia coli bacteria (DSM 17252, cells and autolysate) corresponding to  $1.5 - 4.5 \times 10^7$  viable cells.
- 1 mL = 14 drops
- The other ingredients are: sodium chloride, magnesium sulphate heptahydrate, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate and purified water

### **What Symbioflor 2 looks like and contents of the pack**

Symbioflor 2 is a colourless, particle-free suspension for oral use.

Symbioflor 2 is packed in 50 mL amber glass bottles with a plastic cap and dropper.

This medicine is available in the following pack sizes:

- 50 mL suspension (N2)
- 2x 50 mL suspension (N3)

### **Marketing Authorisation Holder and Manufacturer**

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**This leaflet was last revised in April 2013.**

### **Other sources of information**

Information for patients on Symbioflor 2 treatment is available from the manufacturer.