

## **PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

### **SYMBIOFLOR® 1**

Oral drops, suspension

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

#### **1. WHAT SYMBIOFLOR® 1 IS AND WHAT IT IS USED FOR**

Enterococcus faecalis bacteria are living bacteria with a positive effect on the immune system.

Symbioflor® 1 is to be used to reduce the relapse rate for recurrent infections of the upper and lower respiratory tracts, particularly inflammation of the nasal sinuses (sinusitis) and bronchi (bronchitis).

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SYMBIOFLOR® 1**

Symbioflor® 1 must not be taken if you are hypersensitive (allergic) to bacterial culture containing Enterococcus faecalis bacteria or any of the other ingredients of this medicine listed in section 6.

#### **Warnings and precautions**

You must talk to your doctor if you experience adverse reactions or become pregnant. Symbioflor® 1 is not suitable for the treatment of symptoms associated with acute conditions affecting the respiratory tract. There are no controlled studies for patients under 18 or over 65 years of age.

#### **Other medicines and Symbioflor® 1**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Antibiotics may inhibit the Enterococcus faecalis bacteria and thereby reduce the effectiveness of this medicine. Speak to your doctor therefore before taking Symbioflor® 1 at the same time as antibiotics.

#### **Symbioflor® 1 with food and drink**

There are no restrictions.

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

Although Symbioflor® 1 is not known to have any effects which cause foetal malformation (teratogenic effects), the product should only be used during pregnancy and breast-feeding after careful consideration of the benefits and risks by your doctor.

#### **Driving and using machines**

Symbioflor® 1 has no influence on the ability to drive and use machines.

#### **Symbioflor® 1 contains lactose and glucose.**

Always consult your doctor before taking Symbioflor® 1 if you know you have an intolerance to certain sugars.

#### **3. HOW TO TAKE SYMBIOFLOR® 1**

Always take Symbioflor® 1 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Unless the doctor says otherwise, the recommend dose for adults aged 18 and over is 30 drops 3 times a day. Take Symbioflor® 1 in the morning after getting up, at midday before eating and in the evening before going to bed. Keep Symbioflor® 1 in your mouth for a minute and gargle before swallowing.

Shake well before use. This makes the liquid slightly cloudy. The clearly noticeable smell of the solution, which is sometimes found to be unpleasant, is characteristic of the product and may vary in strength.

Symbioflor® 1 does not contain any stabilisers and is therefore easily contaminated if not handled correctly. Such contamination is avoided by only opening the bottle briefly when using the product and by allowing the contents to flow carefully drop by drop from the dropper. Do not touch the dropper!

Due to the high surface tension of Symbioflor® 1, problems cannot be entirely avoided when starting and stopping release of the drops. Lightly tapping the base of the bottle while holding it at an angle will cause the drops to flow more easily. The rate of flow can be influenced by varying the angle at which the bottle is held.

The duration of the treatment will depend on the course taken by the medical condition concerned and may be as long as 6 months for chronic infections.

**If you take more Symbioflor® 1 than you should**, there is no need to take any countermeasures.

**If you forget to take Symbioflor® 1**, do not take a double dose to make up for a forgotten dose, but continue taking the medicine at the original dose prescribed.

**If you stop taking Symbioflor® 1**, no particular measures are required. Talk to your doctor if necessary.

If you have any further questions about how to use the medicine, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine may also produce side effects, although these may not necessarily affect every person.

Very rare (affects less than 1 in 10,000 people):

- |                        |             |                  |   |
|------------------------|-------------|------------------|---|
| - Headache             | - Vomiting  | - Rashes         | - Painful, persistent swelling of the skin and mucosa |
| - Dryness of the mouth | - Diarrhoea | - Skin reactions | (angioedema)  |
| - Stomach ache         | - Urticaria |                  |   |
| - Nausea               | - Itchiness |                  |   |

#### 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 any 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

Abt. Pharmakovigilanz, 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® 1

Store **Symbioflor® 1** below 30°C before opening. Do not freeze. Close the bottle properly immediately after use and keep in the refrigerator (2°C – 8°C). The contents keep for 4 weeks after the bottle is opened for the first time.

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

Do not use this medicine if you notice the following:

Stop taking **Symbioflor® 1** if the solutions shows noticeable signs of clumping or flocculation.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

##### What Symbioflor® 1 contains

- The active substance is: bacteria culture (1.0 ml) containing Enterococcus faecalis bacteria (DSM 16440, cells and autolysate) equivalent to 1.5 – 4.5 x 10<sup>7</sup> living cells.
- 1 ml = 12 drops
- The other ingredients are: lactose monohydrate, cystine, sodium carbonate decahydrate, sodium chloride, magnesium sulphate heptahydrate, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, purified water, standard I nutrient broth (peptone [from casein], yeast extract, sodium chloride, glucose monohydrate, purified water)

##### What Symbioflor® 1 looks like and contents of the pack

**Symbioflor® 1** is a golden-yellow particle-free suspension for internal use. **Symbioflor® 1** comes in 50 ml bottles made of brown glass with a plastic cap and dropper.

This medicine is available in the following pack sizes:

50 ml suspension (N1)

2 x 50 ml suspension (N2)

3 x 50 ml suspension (N3)

##### Marketing Authorisation Holder and Manufacturer

SymbioPharm GmbH, Auf den Lüppen 10, 35745 Herborn, Germany

Tel.: 02772 981-300, fax: 02772 981-301, email: [info@symbiopharm.de](mailto:info@symbiopharm.de)

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

##### Other sources of information

Patients can obtain information material on treatment with **Symbioflor® 1** from the manufacturer.

