

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

PRO-SYMBIOFLOR®

Oral drops, suspension

Bacterial lysate prepared from *Enterococcus faecalis* and *E. coli*

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 notice any side effects, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- Consult your doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Pro-Symbioflor® is and what it is used for

2. What you need to know before you take Pro-Symbioflor®

3. How you take Pro-Symbioflor®

4. Possible side effects

5. How you store Pro-Symbioflor®

6. Contents of the pack and other information

1. WHAT PRO-SYMBIOFLOR® IS AND WHAT IT IS USED FOR

Pro-Symbioflor® is a bacterial lysate (killed bacterial culture) that is prepared from *Enterococcus faecalis* and *Escherichia coli* bacteria and has a positive effect on the immune system. Pro-Symbioflor® is administered in the case of gastrointestinal disorder and irritable bowel syndrome.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRO-SYMBIOFLOR®

Pro-Symbioflor® must not be taken

- if you are allergic to the bacterial lysate prepared from *Enterococcus faecalis* and *E. coli* or to any of the other ingredients of this medicine listed in section 6.

Warnings and precautions

Please consult your doctor or pharmacist before taking Pro-Symbioflor®.

Taking Pro-Symbioflor® together with other medicines

There are no known interactions with other medicines.

Taking Pro-Symbioflor® together with food and drink

There are no restrictions.

Pregnancy and breastfeeding

Consult your doctor or pharmacist before taking this medicine if you are pregnant or breastfeeding, if you suspect that you could be pregnant or if you are planning a pregnancy.

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

Driving and using machines

Pro-Symbioflor® has no or negligible influence on the ability to drive and use machines.

Pro-Symbioflor® contains lactose and glucose.

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

3. HOW YOU TAKE PRO-SYMBIOFLOR®

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

The recommended dose is:

Adults take 5 drops, 3 times a day at the beginning of the treatment. Within 2 weeks, the dose is increased to 20 drops, 3 times a day.

Shake Pro-Symbioflor® well before use! This will cause slight clouding.

Take Pro-Symbioflor® dissolved in some water along with your meals.

Pro-Symbioflor® 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 Pro-Symbioflor®, 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 cases.

Use in children and adolescents

Adjust the dosage for children as needed (e.g. 5 drops, 3 times a day for children and adolescents at the start, increase to 10 drops, 3 times a day within 2 weeks).

If you have taken a higher dose of Pro-Symbioflor® than that prescribed,
no action is required.

If you forget to take Pro-Symbioflor®,

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 Pro-Symbioflor®,

no special measures are required. Consult your doctor if necessary.

If you have any further questions about taking this 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.

Pro-Symbioflor® is generally well tolerated. The following undesirable effects may occur, however:

Occasional (affects less than 1 in 1000 patients):

- flatulence
- upper abdominal complaints

Reporting of side effects

If you notice any side effects, consult 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: www.bfarm.de

5. HOW YOU STORE PRO-SYMBIOFLOR®

Do not store Pro-Symbioflor® above +30°C before opening the bottle. Do not freeze. Close the bottle properly immediately after use and keep in the refrigerator (2°C – 8°C). The contents keep for at least 3 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: strong flocculation of the solution.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pro-Symbioflor® contains

The active substance is: bacterial lysate prepared from

- 1.5 - 4.5 x 10⁷ cells of *Enterococcus faecalis* (DSM 16440)
- 1.5 - 4.5 x 10⁷ cells of *E. coli* (DSM 17252)

- 1 ml = 14 drops

- The other ingredients are: lactose monohydrate, sodium carbonate decahydrate, sodium chloride, magnesium sulphate heptahydrate, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, nutrient broth (peptone, yeast extract, sodium chloride, glucose monohydrate), purified water.

What Pro-Symbioflor® looks like and contents of the pack

Pro-Symbioflor® is a golden-yellow particle-free suspension for internal use.

Pro-Symbioflor® 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 (N2) 2 x 50 ml suspension (N3)

Pharmaceutical company and manufacturer

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

Tel.: +49 (0)2772 981-300, fax: +49 (0)2772 981-301, email: info@symbiopharm.de

This leaflet was last revised in June 2014.

Other sources of information

Patients can obtain information material on treatment with Pro-Symbioflor® from the manufacturer.