Internal, unofficial translation of the German package leaflet

**Patient Information Leaflet:**
**Information for users**

**Perenterol®**
**50 mg capsules**

For children aged 2 and over and adults
Saccharomyces cerevisiae dried yeast

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**Read all of this leaflet carefully before you start taking this medicine because it contains important information.** Always take this medicine exactly as described in this leaflet, or exactly as instructed by your doctor or pharmacist.

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

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

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1. **What Perenterol is and what it is used for**
Perenterol is a medicine containing 50 mg of dried yeast to be taken for diarrhoea and for acne.

Perenterol is used for the:
- treatment of symptoms in acute diarrhoeal illnesses.
- prevention and treatment of travellers' diarrhoea and diarrhoea associated with tube feeding.
- concomitant treatment in prolonged forms of acne.

2. **What you need to know before you take Perenterol**
   **Do not take Perenterol 50 mg capsules**
   if you are allergic to yeast or any of the other ingredients of this medicine listed in section 6.
   if you are suffering from a life-threatening illness (e.g. complicated illness requiring intensive medical care) or weakened immune defences (e.g. as a result of HIV infection, organ transplant, leukaemia, malignant tumours, radiotherapy, chemotherapy, prolonged high-dose steroid treatment) and/or if you have a central venous catheter.

   In such cases, the risk of colonization of the whole body (generalized colonization) with Saccharomyces boulardii cannot be assessed at the present time.

   Self-medication is prohibited in infants and toddlers under 2 years of age since diarrhoea in infants or toddlers requires a consultation with a doctor.
**Warnings and precautions**
Talk to your doctor or pharmacist before taking Perenterol, if you suffer from serious underlying illnesses, particularly those involving the gastrointestinal tract.

Saccharomyces boulardii is a live microorganism which, under unfavourable conditions, e.g. those found in immunocompromised patients, can cause generalized fungal infections through migration from the gastrointestinal tract to the circulation, or through external contamination of central venous catheters. Isolated cases of such fungal infections have been reported in hospital patients who had a central venous catheter, were suffering from life-threatening or serious underlying illnesses (usually involving the gastrointestinal tract) or who had severely weakened immune defences.

If the diarrhoea persists for more than 2 days, contains blood or is associated with a rise in temperature, you should consult a doctor.

In diarrhoeal illnesses, particularly in children, the replacement of fluids and salts (electrolytes) should be viewed as the most important therapeutic measure.

You should consult a doctor if the acne deteriorates or does not improve.

If, during or shortly after treatment with Perenterol, microbiological stool examinations are performed, you or your doctor should inform the laboratory that you have been taking the product, otherwise false-positive findings may result.

**Taking Perenterol together with other medicines**
Do not take medicines which act in the gastrointestinal tract against fungal illnesses (antimycotics) at the same time as this may impair the efficacy of Perenterol.

Please note that the above can also apply to recently administered preparations.

Inform your doctor or pharmacist if you are taking other medicines, have recently taken other medicines or intend to take any other medicines.

**Taking Perenterol with food, drink and alcohol**
Do not take Perenterol together with alcohol.

**Pregnancy and breast-feeding**
No evidence of risks during pregnancy or breast-feeding has emerged to date from the widespread use of yeast as a food product. Since there are no results from experimental studies with Saccharomyces boulardii, this medicine should not be used during pregnancy or breast-feeding.

**Driving and the ability to use machines**
No precautions are required.

**Perenterol contains lactose and sucrose**
You should therefore take Perenterol only after consulting your doctor if you are unable to tolerate certain sugars.

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

Unless otherwise prescribed by the doctor, the usual dose for children aged 2 and over and adults is as follows:

- for the treatment of acute diarrhoea, 2 - 3 capsules of Perenterol three times a day (equivalent to 300 to 450 mg dried yeast from Saccharomyces boulardii daily).
• for the prevention of traveller's diarrhoea, starting 5 days before departure, 2 - 3 capsules of Perenterol three times a day (equivalent to 300 to 450 mg dried yeast from Saccharomyces boulardii daily).

• for diarrhoea caused by tube feeding, the contents of 15 capsules of Perenterol in 1.5 litres of nutrient solution daily (equivalent to 750 mg dried yeast from Saccharomyces boulardii daily).

• for acne, 5 capsules of Perenterol three times a day (equivalent to 750 mg dried yeast from Saccharomyces boulardii daily).

Swallow the capsules whole before meals with sufficient fluid (preferably a glass of water).

For easier administration, e.g. to children, the capsules can be opened by pulling apart. The capsule contents can be mixed with food or drink. The food and drink should be neither too hot nor ice-cold (room temperature).

Duration of administration
Although, in principle, there are no restrictions on the duration of administration of yeast preparations, please note the "Warnings and precautions" in section 2 and section 4 "Possible side effects".

In cases of diarrhoea, the treatment should continue for a few days after the symptoms have stopped.

For concomitant treatment in chronic forms of acne it is recommended that the preparation be administered for several weeks.

Consult your doctor or pharmacist if you think that the effect of Perenterol is too strong or too weak.

If you take more Perenterol than you should
If you have taken one or two capsules more than you should have by mistake on a single occasion this will not usually have any adverse consequences.

If you have taken a substantial overdose of this medicine, the side effects may be increased (see section 4 "Possible side effects"). In this case you should consult a doctor.

If you forget to take Perenterol
Do not take double the amount to make up for a forgotten dose.

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

Administration can cause flatulence.

Hypersensitivity reactions can also occur in the form of itching, nettle rash (urticaria), rash, either limited to a specific area or affecting the whole body (so-called local or generalized exanthema), as can swelling of the skin and mucous membranes, usually in the facial area (angioedema) Shortness of breath and allergic shock have also been observed.

If you notice any of the above-mentioned hypersensitivity reactions, particularly swelling of the facial mucous membranes (angioedema), shortness of breath or signs of allergic shock, you should stop taking this medicine and tell a doctor (immediately) so that he can decide on the severity and any required measures.

There are reports to indicate that Saccharomyces boulardii can colonize the circulation of patients with an indwelling central venous catheter, a life-threatening illness, severe underlying illness or weakened immune defences.

No statements can be made about the frequency of these possible side effects.
Reporting of side effects
If you notice 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 Federal Institute for Drugs and Medical Devices at the following address: Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Perenterol
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 / carton. The expiry date refers to the last day of the stated month.

Keep the glass bottle firmly closed in order to protect the contents from moisture.

If you open the container and the capsules come into contact with atmospheric moisture, in rare cases the contents of the capsule may turn brown and become hard. If this happens, do not take any more capsules.

6. Contents of the pack and other information
What Perenterol contains
The active substance is Saccharomyces cerevisiae dried yeast.
1 hard capsule contains 50 mg dried yeast from Saccharomyces cerevisiae HANSEN CBS 5926 (in medical parlance also known as Saccharomyces boulardii), equivalent to at least 1.8x10^{10} viable cells/g of lyophilisate.

The other ingredients are lactose monohydrate, sucrose, magnesium stearate (Ph.Eur.), gelatin, sodium dodecyl sulphate, colouring agent: titanium dioxide (E 171).

What Perenterol looks like and contents of the pack
Perenterol 50 mg capsules are white, opaque hard capsules.

Perenterol is available in packs containing 20, 50 hard capsules.

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This leaflet was last revised in March 2014.