Internal, unofficial translation of the German package leaflet

Patient Information Leaflet:
Information for users

Perenterol®
50 mg capsules
Saccharomyces cerevisiae HANSEN CBS 5926 dried yeast

For children aged 2 and over and adults

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.

What is in this leaflet

1. What Perenterol® is and what it is used for
Perenterol® is a medicine containing 50 mg dried yeast from *Saccharomyces cerevisiae* HANSEN CBS 5926 (in medical terms also called *Saccharomyces boulardii*) that is used to treat diarrhoea and 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 have a central venous catheter
- if you have a weakened immune system or if you are in hospital (due to severe illness or impaired/weakened immune system)

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.
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.

Very rare side effect (affecting up to 1 in 10,000 patients treated):
- Presence of yeast in the blood stream (fungaemia)

Not known: The frequency of these possible side effects cannot be estimated from the available data:
- Use may cause flatulence.
- Hypersensitivity reactions may also occur in the form of itching, hives (urticaria) and rash, either limited to a specific area or affecting the whole body (so-called local or generalised rash), as well as swelling of the skin and mucous membranes, usually in the region of the face (angioedema). Shortness of breath and allergic shock have also been observed.
  If you notice any of the hypersensitivity reactions mentioned above, particularly swelling of the mucous membranes of the face (angioedema), shortness of breath or signs of allergic shock, stop taking this medicine and tell a doctor (immediately), so that they can determine the severity of the symptoms and decide whether any treatment measures are required.

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* HANSEN CBS 5926 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 and 100 hard capsules.

Marketing Authorisation Holder and manufacturer

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