

Internal, unofficial translation of the German package leaflet

**Patient Information Leaflet:
Information for users**

**Perenterol[®]
forte 250 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[®] forte 250 is and what it is used for
2. What you need to know before you take Perenterol[®] forte
3. How to take Perenterol[®] forte
4. Possible side effects
5. How to store Perenterol[®] forte
6. Contents of the pack and other information

1. What Perenterol[®] forte is and what it is used for

Perenterol[®] forte is a medicine containing 250 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[®] forte 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[®] forte

Do not take Perenterol[®] forte

- 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[®] forte, 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[®] forte, 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[®] forte 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 the Perenterol[®] forte. 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[®] forte with food, drink and alcohol

Do not take Perenterol[®] forte 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[®] forte contains lactose

You should therefore take Perenterol[®] forte only after consulting your doctor if you are unable to tolerate certain sugars.

3. How to take Perenterol[®] forte

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, 1 capsule of Perenterol[®] forte once or twice a day (equivalent to 250 to 500 mg dried yeast from *Saccharomyces boulardii* daily).
- for the prevention of traveller's diarrhoea, starting 5 days before departure, 1 capsule of Perenterol[®] forte once or twice a day (equivalent to 250 to 500 mg dried yeast from *Saccharomyces boulardii* daily).
- for diarrhoea caused by tube feeding, the contents of 3 capsules of Perenterol[®] forte in 1.5 litres of nutrient solution daily (equivalent to 750 mg dried yeast from *Saccharomyces boulardii* daily).
- for acne, 1 capsule of Perenterol[®] forte three times a day (equivalent to 750 mg dried yeast from *Saccharomyces boulardii* daily).

Method of administration

First detach an individual blister from the strip and then carefully pull back the blister foil from the corner until the capsule is exposed in its blister. The capsule can now be taken out of the blister.

Do not press the capsule through the blister foil as this may cause the capsule to break. Repeat this process to remove additional capsules.

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[®] forte 250 mg capsules is too strong or too weak.

If you take more Perenterol[®] forte 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[®] forte

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® forte

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 blister / carton. The expiry date refers to the last day of the stated month.

6. Contents of the pack and other information

What Perenterol® forte contains

- The active substance is *Saccharomyces cerevisiae* HANSEN CBS 5926 dried yeast. 1 hard capsule contains 250 mg dried yeast from *Saccharomyces cerevisiae* HANSEN CBS 5926 (in medical parlance also known as *Saccharomyces boulardii*), equivalent to at least 1.8×10^{10} viable cells/g of lyophilisate.
- The other ingredients are lactose monohydrate, magnesium stearate (Ph.Eur.), gelatin, sodium dodecyl sulphate, colouring agent: titanium dioxide (E 171).

What Perenterol® forte looks like and contents of the pack

Perenterol® forte 250 mg capsules are white, opaque hard capsules.

Perenterol® forte 250 mg capsules is available in packs containing 10, 20, 30, 50, 60, 100 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

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