

PERENTEROL[®]

forte 250 mg capsules

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

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to take Perenterol forte 250 mg capsules in accordance with the instructions to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You should in any case consult a doctor if your symptoms deteriorate or if no improvement occurs after 2 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Perenterol forte 250 mg capsules is and what it is used for
2. What you need to know before you take Perenterol forte 250 mg capsules
3. How to take Perenterol forte 250 mg capsules
4. Possible side effects
3. How to store Perenterol forte 250 mg capsules
6. Further information

1. WHAT PERENTEROL FORTE 250 MG CAPSULES IS AND WHAT IT IS USED FOR

Perenterol forte 250 mg capsules is a medicine containing dried yeast for diarrhoea and acne.

Perenterol forte 250 mg capsules 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 250 MG CAPSULES

Do not take Perenterol forte 250 mg capsules

- if you are hypersensitive (allergic) to yeast or any of the other ingredients of Perenterol forte 250 mg capsules.
- 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.

Take special care with Perenterol forte 250 mg capsules in the following situations

- 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 forte 250 mg capsules, 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 250 mg capsules 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 250 mg capsules.

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

Please inform your doctor or pharmacist if you are taking / using, or have recently taken / used, other medicines, including non-prescription preparations.

Taking Perenterol forte 250 mg capsules with food and drink

Do not take the capsules 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 using machines

No precautions are required.

Important information about some of the ingredients of Perenterol forte 250 mg capsules

Since this medicine contains lactose, you should take Perenterol forte 250 mg capsules only after consulting your doctor if you are unable to tolerate certain sugars.

3. HOW TO TAKE PERENTEROL FORTE 250 MG CAPSULES

Always take Perenterol forte 250 mg capsules exactly as described in this leaflet. 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 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 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 in 1.5 litres of nutrient solution daily (equivalent to 750 mg dried yeast from *Saccharomyces boulardii* daily).
- for acne, 1 capsule 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 administration to children under 6 years of age the capsules should be opened by pulling apart and the contents 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 information in section 2 "Take special care with Perenterol forte 250 mg capsules in the following situations..." 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 250 mg capsules 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 250 mg capsules

Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Perenterol forte 250 mg capsules can 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.

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.

If you notice side effects, particularly those not listed in this package insert, please inform your doctor or pharmacist.

What countermeasures should be taken in the event of side effects?

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

5. HOW TO STORE PERENTEROL FORTE 250 MG CAPSULES

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the label / carton. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Perenterol forte 250 mg capsules contains

The active substance is *Saccharomyces cerevisiae* 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 250 mg capsules 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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