

# PERENTEROL®

## 50 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 50 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 50 mg capsules is and what it is used for
2. What you need to know before you take Perenterol 50 mg capsules
3. How to take Perenterol 50 mg capsules
4. Possible side effects
5. How to store Perenterol 50 mg capsules
6. Further information

### **1. WHAT PERENTEROL 50 MG CAPSULES IS AND WHAT IT IS USED FOR**

Perenterol 50 mg capsules is a medicine containing dried yeast for diarrhoea and acne.

Perenterol 50 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 50 MG CAPSULES**

#### **Do not take Perenterol 50 mg capsules**

- if you are hypersensitive (allergic) to yeast or any of the other ingredients of Perenterol 50 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 50 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 50 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 50 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 50 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 50 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 50 mg capsules**

Since this medicine contains lactose and sucrose, you should take Perenterol 50 mg capsules only after consulting your doctor if you are unable to tolerate certain sugars.

### **3. HOW TO TAKE PERENTEROL 50 MG CAPSULES**

Always take Perenterol 50 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, 2 - 3 capsules 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 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 in 1.5 litres of nutrient solution daily (equivalent to 750 mg dried yeast from *Saccharomyces boulardii* daily).
- for acne, 5 capsules 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 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 50 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 50 mg capsules is too strong or too weak.

#### **If you take more Perenterol 50 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 50 mg capsules**

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



#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Perenterol 50 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 of any required measures.

#### **5. HOW TO STORE PERENTEROL 50 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.

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. FURTHER INFORMATION**

##### **What Perenterol 50 mg capsules 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  $1.8 \times 10^{10}$  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 50 mg capsules looks like and contents of the pack**

Perenterol 50 mg capsules are white, opaque hard capsules.

Perenterol 50 mg capsules is available in packs containing 20, 50, 100 hard capsules.

##### **Marketing Authorisation Holder and manufacturer**

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