

PERENTEROL[®]

Junior 250 mg powder

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

1. WHAT PERENTEROL JUNIOR 250 MG POWDER IS AND WHAT IT IS USED FOR

Perenterol Junior 250 mg powder is a medicine containing dried yeast for diarrhoea and acne.

Perenterol Junior 250 mg powder 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 JUNIOR 250 MG POWDER

Do not take Perenterol Junior 250 mg powder

- if you are hypersensitive (allergic) to yeast or any of the other ingredients of Perenterol Junior 250 mg powder.
- if you are suffering from a life-threatening illness (e.g. complicated illness requiring intensive medical care) or a weakened immune defence (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 Junior 250 mg powder 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 Junior 250 mg powder, 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 Junior 250 mg powder 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 Junior 250 mg powder.

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 Junior 250 mg powder with food and drink

Do not take the contents of the sachets 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 Junior 250 mg powder

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

3. HOW TO TAKE PERENTEROL JUNIOR 250 MG POWDER

Always take Perenterol Junior 250 mg powder exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

Divide the double sachet at the perforation into two individual sachets. The following dosage directions apply to the individual sachets.

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

Stir the sachet contents into plenty of water or other drink or mix with food, which should not be too hot (not above 50 °C) or ice-cold.

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 Junior 250 mg powder 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 Junior 250 mg powder is too strong or too weak.

If you take more Perenterol Junior 250 mg powder than you should

If you have taken one or two sachets 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 Junior 250 mg powder

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



4. POSSIBLE SIDE EFFECTS

Like all medicines, Perenterol Junior 250 mg powder 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 JUNIOR 250 MG POWDER

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 sachet / carton. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Perenterol Junior 250 mg powder contains

The active substance is *Saccharomyces cerevisiae* dried yeast.

1 sachet 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, fructose (Ph.Eur.), colloidal silica, tutti-frutti flavouring, powder, synthetic.

What Perenterol Junior 250 mg powder looks like and contents of the pack

Perenterol Junior 250 mg powder is a creamy white powder in a double sachet with perforation.

Perenterol Junior 250 mg powder is available in packs containing 10, 20, 50, 100 sachets.

Marketing Authorisation Holder and manufacturer

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This leaflet was last revised in November 2012.

Internal, unofficial translation of the German package leaflet.

