

Internal, unofficial translation of the German package leaflet

**Patient Information Leaflet:
Information for users**

**Perenterol[®]
Junior 250 mg powder**

Saccharomyces cerevisiae HANSEN CBS 5926 dried yeast

For the treatment of diarrhoea in adults and children over 6 months

For the prevention of travellers' diarrhoea in adults and children over 12 years

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

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

Perenterol[®] Junior is a medicine containing 250 mg dried yeast from *Saccharomyces cerevisiae* HANSEN CBS 5926 (in medical terms also called *Saccharomyces boulardii*) in the form of a powder for oral use.

Perenterol[®] Junior is used:

- to treat the symptoms of acute diarrhoea, including travellers' diarrhoea and diarrhoea associated with tube feeding
- to prevent travellers' diarrhea

2. What you need to know before you take Perenterol[®] Junior

Do not take Perenterol[®] Junior

- 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)

Warnings and precautions

Talk to your doctor or pharmacist before taking Perenterol[®] Junior, 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. If, during or shortly after treatment with Perenterol[®] Junior, 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.

Children and adolescents

This medicine should not be used to treat diarrhoea in infants under the age of 6 months, as studies of dose levels and safety are inadequate. Please consult a doctor before treating infants and young children under the age of 2 years.

This medicine should not be used to prevent travellers' diarrhoea in children under the age of 12 years, as not enough studies have been performed.

Taking Perenterol[®] Junior 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[®] Junior. 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[®] Junior with food, drink and alcohol

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 the ability to use machines

No precautions are required.

Perenterol[®] Junior contains lactose and fructose

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

3. How to take Perenterol[®] Junior

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.

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 is as follows:

	For acute diarrhoea	For prevention of travellers' diarrhoea
Infants and young children between 6 months and 2 years	Once or twice daily 1 sachet Perenterol® Junior Treatment should only take place after consulting a doctor	Use is not indicated
Children between 2 years and 11 years of age (inclusive)	Once or twice daily 1 sachet Perenterol® Junior	Use is not indicated
Adults and children aged 12 years and over	Once or twice daily 1 sachet Perenterol® Junior	Starting 5 days before travel, 1 sachet Perenterol® Junior once or twice 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

Please see 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 prevention of travellers' diarrhoea, treatment should be taken regularly over the entire period of travel.

Consult your doctor or pharmacist if you think that the effect of Perenterol® Junior is too strong or too weak.

If you take more Perenterol® Junior 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

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 and constipation.
- 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 side effects 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® Junior

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 sachet and carton after "Expiry date" or "EXP". The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Perenterol® Junior contains

- The active substance is *Saccharomyces cerevisiae* HANSEN CBS 5926 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 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 is available in packs containing 10, 20, 50 and 100 sachets.

Marketing Authorisation Holder and manufacturer

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