

Yomogi® 250 mg

Hard capsules

Use in case of diarrhea in adults, adolescents and children from the age of 6 months
For prevention of traveler's diarrhea in adults and adolescents from the age of 12 years



Active substance: *Saccharomyces cerevisiae* HANSEN CBS 5926 - dry yeast

**Read all of this leaflet carefully because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.**

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

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1. What Yomogi® 250mg is and what it is used for

- 1.1 Yomogi® 250mg contains viable dry yeast from cultures of the defined strain *Saccharomyces cerevisiae* HANSEN CBS 5926 (in medical language use also referred to as *Saccharomyces boulardii*) and belongs to the group of the antidiarrheals.
- 1.2 For the treatment of symptoms of acute diarrhea, also in case of traveler's diarrhea and diarrhea during feeding by stomach tube.
For the prevention of traveler's diarrhea

2. What you need to know before you take Yomogi® 250mg

2.1 Do not take Yomogi® 250mg

- If you are allergic to yeast or any of the other ingredients of this medicine (listed in section 6).
Due to the as yet not assessable risk of a systemic colonization with *Saccharomyces cerevisiae* HANSEN CBS 5926
- patients with a heavily impaired immune defense system (e.g. HIV infections, organ transplantation, leukemia, malignant tumors, radiotherapy, chemotherapy, long-term large-dose cortisone treatment) and
- patients with a central venous catheter should not use this drug.

2.2 Warnings and precautions

Talk to your doctor or pharmacist before taking Yomogi® 250mg.
With diarrhea lasting longer than 2 days or accompanied by blood in the stool or a rise in temperature, you should consult a doctor.
With diarrheal diseases, especially in children, attention must be paid to the use of fluid and electrolytes as the most important therapeutic measure.
If microbiological stool examinations are carried out during or shortly after treatment with this medicinal product, the examining laboratory should be informed about the treatment because otherwise false-positive results may be obtained.

2.3 Children and adolescents

For the use in of diarrhea, this medicinal product should not be used in infants under 6 months of age because no adequate dosage and safety studies are available.
The treatment of diarrhea in infants and toddlers requires the consultation with the doctor.
For the treatment of traveler's diarrhea this medicinal product should not be used in children under the age of 12 years because of inadequate studies.

2.4 Other medicines and Yomogi® 250mg

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines.
The concomitant use of Yomogi® 250mg and antimycotic medicinal products may impair the effect of Yomogi® 250mg.
The concomitant use of monoamino-oxidase inhibitors may increase the blood pressure.

2.5 Pregnancy and breast-feeding

The safety during pregnancy and breast-feeding was not sufficiently investigated. It is not recommended to use Yomogi® 250mg during pregnancy and breast-feeding.

2.6 Driving and using machines

Without restriction.

2.7 Important information about some of the ingredients of Yomogi® 250mg

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Yomogi® 250mg

Always take Yomogi® 250mg exactly as your doctor has told. You should check with your doctor or pharmacist if you are not sure.

3.1 Dosage

The recommended dose is:

For acute diarrhea

Children between 6 months and 2 years:

1 hard capsule 1 – 2 times daily

In children of this age group, the treatment must be carried out under medical supervision.

Children from 2 years, adolescents and adults:

1 hard capsule 1 – 2 times daily

Infants under 6 months:

The application is not provided.

For prevention of traveler's diarrhea

Adolescents from 12 years and adults:

1 hard capsule 1 – 2 times daily starting 5 days before the departure.

Children under 12 years:

The application is not provided.

3.2 Method of administration

For oral use.

Please take the hard capsules unchewed with an appropriate amount of fluid (preferably a glass of water) before the meals.

In children under 6 years of age, the hard capsule is opened by pulling it apart and the contents stirred into food or liquid (room temperature).

In diarrhea induced by tube feeding, only the content of the hard capsules has to be added to the nutrient solution.

3.3 Duration of treatment

For the treatment of symptoms of acute diarrhea, normally the intake of Yomogi® 250mg over a period of 4 to 7 days is sufficient.

For the prevention of traveler's diarrhea, treatment should be carried out consistently over the entire travel duration.

Please, definitely pay attention to the details under section **2.2** "Warnings and precautions" and section **4** "Possible side effects".

3.4 If you take more Yomogi® 250mg than you should

Intoxications with preparations of dry yeast have not been reported so far.

If you have taken more Yomogi® 250mg than recommended, you should tell your doctor who can decide to take measures, if necessary.

The below mentioned side effects may occur to an increased extent.

3.5 If you forget to take Yomogi® 250mg

Do not take a double dose to make up for a forgotten dose. Taking of Yomogi® 250mg should be continued as prescribed by your doctor or described in this package leaflet.

3.6 If you stop taking Yomogi® 250mg

You can stop or discontinue taking Yomogi® 250mg at any time because discontinuation can generally be regarded as harmless.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

For the assessment of side effects, the following data on frequency are used as a basis:

Very common:	more than 1 of 10 patients treated
Common:	less than 1 of 10 but more than 1 of 100 patients treated
Uncommon:	less than 1 of 100 but more than 1 of 1,000 patients treated
Rare:	less than 1 of 1,000 but more than 1 of 10,000 patients treated
Very rare:	Frequency cannot be estimated from the available data

4.1 Possible side effects

Taking this drug may cause flatulence.

Also, intolerance reactions in the form of pruritus, wheals (urticaria), skin rash either localized or over the whole body (so-called local or generalized exanthema) as well as swelling of the skin and mucosa mostly in the facial region (Quincke's edema), shortness of breath, and allergic shock may occur.

The frequencies of these possible side effects cannot be predicted.

4.2 Actions to be taken in case of side effects

If you notice one of the above-mentioned side effects, especially swelling of the mucosa in the facial region (Quincke's edema), shortness of breath, or signs of allergic shock, stop taking this drug and (immediately) inform a doctor so that he/she can decide on the degree of severity and any treatment measures which might be required.

At the first evidence for a hypersensitive (allergic) reaction, Yomogi® 250mg must not be taken for a further time.

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

4.3 Reporting of side effects

If you get any 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 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 Yomogi® 250mg

Do not store above 25 °C.

Keep out of the reach and sight of children.

Do not use Yomogi® 250mg after the expiry date which is stated on the outer carton and on the blister.

6. Content of the pack and other information

6.1 What Yomogi® 250mg contains

The active substance is:

1 hard capsule contains:

250 mg dry yeast of *Saccharomyces cerevisiae* HANSEN CBS 5926 (in medical language use also referred to as *Saccharomyces boulardii*) corresponding to min. 2×10^{10} viable cells / g, lyophilized.

The other ingredients are:

Lactose, magnesium stearate Ph. Eur. [vegetable], hypromellose, purified water, titanium dioxide (E 171). For diabetics, taking 1 hard capsule Yomogi® 250mg should be calculated as 0.01 carbohydrate exchange units.

6.2 What Yomogi® 250mg looks like and contents of the pack

Appearance: White hard capsules

Packs:

Original packs with 10 hard capsules

Original packs with 20 hard capsules

Original packs with 50 hard capsules

Original packs with 100 hard capsules

6.3 Marketing authorisation holder and manufacturer

Ardeypharm GmbH, Loerfeldstraße 20, 58313 Herdecke, Germany, Phone: +49 (0) 23 30 / 977 677

This leaflet was last approved in December 2015.

Dear Patient!

It is possible that the leaflet in your medicine pack may differ from this version.

This leaflet is an internal, unofficial translation of the German package leaflet and may not apply to other countries.