

Package Insert Leaflet

Please read the entire package insert leaflet carefully because it contains important information for you.

In order to achieve the best possible treatment success Yomogi must be used as advised.

- Please keep this package insert leaflet. Perhaps you would like to read it once again later.
- Please ask your pharmacist if you need further information or advice.
- If your clinical picture worsens or has not improved after 2 days, please consult a doctor.

This package insert leaflet contains:

1. What is Yomogi and what is it used for?
2. What do you have to consider before taking Yomogi?
3. How should Yomogi be taken?
4. Which side effects possibly occur?
5. How should Yomogi be stored?

Yomogi

Active substance: the medicinally active ingredient is dry yeast of *Saccharomyces boulardii* (synonym: *Saccharomyces cerevisiae* Hansen CBS 5926)

1 hard capsule contains:

250 mg dry yeast of *Saccharomyces boulardii* (synonym: *Saccharomyces cerevisiae* HANSEN CBS 5926) with at least 10^{10} viable cells/g, freeze-dried

The other substances are:

Anhydrous lactose, magnesium stearate, gelatin, water, colorants E 141, E 171, E 172

For diabetics, taking 1 hard capsule Yomogi should be counted as 0.01 carbohydrate exchange units.

Yomogi is available in packs containing 20 and 50 hard capsules.

1. WHAT IS YOMOGI AND WHAT IS IT USED FOR?

1.1 Yomogi contains dry yeast.

1.2 From:

Ardeypharm GmbH
Loerfeldstraße 20
58313 Herdecke, Germany
Telephone: (02330) 977677

1.3 Yomogi is used for the treatment of symptoms of acute diarrhea, prevention and treatment of symptoms of traveler's diarrhea as well as diarrhea during feeding by stomach tube, and for concomitant treatment with more persistent forms of acne.

2. WHAT DO YOU HAVE TO CONSIDER BEFORE TAKING YOMOGI?

2.1 Yomogi should not be taken

If you are hypersensitive (allergic) to yeast or one of the other substances.

Due to the as yet not assessable risk of a systemic colonization with *Saccharomyces boulardii*, patients with a weakened 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 without seeking medical advice.

2.2 Special caution is required when taking Yomogi

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.

With worsening or absence of improvement of acne, you should consult a doctor.

a) In children

No adequate studies are available on the use of this drug in infants and small children. Therefore, it should not be used in children under 2 years of age.

b) Pregnancy and lactation period

Based on the widespread use of yeast as a foodstuff, there are no indications of risks in pregnancy and the lactation period. Results of experimental studies on *Saccharomyces boulardii* are not available.

d) Ability to drive and operate machines

No special precautions are necessary.

e) Important warnings for certain other ingredients of the drug.

Saccharomyces boulardii is a living microorganism which, under unfavorable conditions as occur in immunocompromised patients, may cause generalized fungal infections via a migration from the gastrointestinal tract into the blood stream or via external contamination of central venous catheters. Individual cases of such fungal infections are known to have occurred in hospitalized patients who had a central venous catheter and at the same time suffered from severe primary diseases (mostly in the gastrointestinal tract).

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 Interactions with other drugs

Please inform your doctor if you are taking other drugs or have taken them until recently even though they are non-prescription drugs.

The effect of the medicinal agents or preparation groups mentioned below may be influenced by the concomitant treatment with this drug:

The concomitant administration of this drug and drugs against fungal diseases (antimycotic agents) may impair the effect of *Saccharomyces boulardii*.

The concomitant administration of monoamino-oxidase inhibitors (drugs against depression) may increase the blood pressure.

2.4 Nothing special must be considered when taking Yomogi together with food and drinks.

3. HOW SHOULD YOMOGI BE TAKEN?

Please always take Yomogi exactly as advised in this package insert leaflet. If you are not entirely sure, please ask your doctor or pharmacist.

3.1 Method of administration

For oral administration

3.2 Unless otherwise prescribed by the doctor, the usual dose is:

Children over the age of 2 and adults take the following:

- For the treatment of diarrhea, 1 hard capsule 1 – 2 times daily equivalent to 250 to 500 mg dry yeast of *Saccharomyces boulardii*

- For prevention of traveler's diarrhea, 1 hard capsule 1 – 2 times daily equivalent to 250 to 500 mg dry yeast of *Saccharomyces boulardii* starting 5 days before the departure

- For diarrhea induced by stomach tube feeding, 3 capsules daily equivalent to 750 mg dry yeast of *Saccharomyces boulardii* in 1.5 liters nutrient solution

- For acne, 1 hard capsule 3 times daily equivalent to 750 mg dry yeast of *Saccharomyces boulardii*

Please do not take hard capsules when lying down.

Please swallow the hard capsules whole with sufficient liquid (preferably a glass of drinking water).

In children under 6 years of age, the hard capsule can also be opened by pulling it apart and the contents stirred into liquid (room temperature) to make the preparation easier to take.

Please talk with your doctor or pharmacist if you have the impression that the effect of this drug is too strong or too weak.

How long should you take Yomogi?

In principle, no limitations of the duration of use are known for taking yeast preparations. However, please consider the information in section 2.2 "Special caution".

The treatment of diarrhea should be continued for a few days after subsidence of the symptoms.

For concomitant treatment of chronic forms of acne, it is advisable to take the capsules for several weeks.

Please also consider the information in section 2.2.

3.3 If you have taken a larger quantity of Yomogi than you should have done:

If you have inadvertently taken one or two hard capsules more than recommended, this usually has no disadvantageous consequences.

If you have considerably overdosed this medicinal product, side effects may occur to an increased extent (see "Side effects"). In this case, you should consult a doctor.

3.4 If you have forgotten to take Yomogi:

Instead of taking a double dose the next time, continue taking the capsules as prescribed by your doctor or described in this package insert leaflet.

4. WHICH SIDE EFFECTS POSSIBLY OCCUR?

Like all drugs, this drug may have side effects.

The list includes all known side effects of treatment with dry yeast, also those under higher doses or long-term treatment.

The assessment of the undesirable effects is based on the following criteria of frequency:

Very common: > 1 of 10 patients treated	Common: More than 1 of 100 patients treated
Uncommon: > 1 of 1,000 patients treated	Rare: More than 1 of 10,000 patients treated
Very rare: 1 or less of 10,000 patients treated, including individual cases	

Taking this drug may often cause flatulence.

Intolerance reactions in the form of pruritus, hives (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 in very rare cases.

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.

Please inform your doctor or pharmacist if you notice side effects than are not mentioned in this package insert leaflet.

5. HOW SHOULD YOMOGI BE STORED?

Keep drugs out of the reach of children.

You must not use this drug after the expiry date printed on the on the outer carton or container.

Date of this information:

August 2004