

# Yomogi®

250 mg corresponding to min. 2.5 x 10<sup>9</sup> viable cells · Hard capsules

For use in adults, adolescents and children

Active substance:

Dry yeast from *Saccharomyces cerevisiae* HANSEN CBS 5926



**Read all of this leaflet carefully because it contains important information for you.**

**This medicinal product is available without prescription. However, you still need to take Yomogi® carefully to get the best results from it.**

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## In this leaflet

1. What Yomogi® is and what it is used for
2. Before you take Yomogi®
3. How to take Yomogi®
4. Possible side effects
5. How to store Yomogi®
6. Further information

## 1. What Yomogi® is and what it is used for

### 1.1 Mode of action

Yomogi® 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 is used for diarrhea and acne.

### 1.2 Yomogi® is used for

- the treatment of symptoms of acute diarrhea.
- the prevention and treatment of symptoms of traveler's diarrhea as well as diarrhea during feeding by stomach tube.
- the supportive treatment of chronic forms of acne.

## 2. Before you take Yomogi®

### 2.1 Do not take Yomogi®

- If you are hypersensitive (allergic) to yeast or any of the other ingredients of Yomogi®.

#### In children:

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

#### Notice:

Due to the as yet not assessable risk of a systemic colonization with *Saccharomyces boulardii*, 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 Take special care with 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. Diarrhea in infants and small children demands consulting the doctor.

If the acne is worsening or does not improve, you should consult a doctor.

If microbiological stool examinations are carried out during or shortly after treatment with this drug, the examining laboratory should be informed about the treatment because otherwise false-positive results may be obtained

### 2.3 Taking other medicines

The concomitant use of Yomogi® and antimycotic agents may impair the effect of Yomogi®.

#### Notice:

The concomitant administration of monoamino-oxidase inhibitors may increase the blood pressure.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### 2.4 Pregnancy and breast-feeding

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 are not available. Therefore, this medicinal product should not be used during pregnancy and breast feeding.

### 2.5 Driving and using machines

No special precautions are necessary.

### 2.6 Important information about some of the ingredients of Yomogi®

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®

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

### 3.1 Dosage

Unless otherwise prescribed by the doctor, the usual dose for children from 2 years of age and adults is:

- For prevention of traveler's diarrhea, 1-2 hard capsules daily starting 5 days before the departure.
- For the treatment of acute diarrhea, 1-2 hard capsules daily.
- For the treatment of acne, 3 hard capsules daily.
- For diarrhea induced by tube feeding, 750 mg daily (content of 3 hard capsules) in 1.5 liters nutrient solution.

### 3.2 Method of administration

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 as well as at tube feeding, 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 contents of the hard capsules has to be added to the nutrient solution.

### 3.3 Duration of treatment

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

For the supportive treatment of chronic forms of acne, the administration over several weeks is recommended.

In principle, no limitations of the duration of use are known for taking yeast preparations.

Please follow the advice under „Before you take Yomogi®“ and “Possible side effects”.

Please consult your doctor or pharmacist whenever you get the impression of the effect of Yomogi® being too strong or too weak.

### 3.4 If you take more Yomogi® than you should

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

If you have taken more Yomogi® 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®

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

### 3.6 If you stop taking Yomogi®

You can stop or discontinue taking Yomogi® 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, Yomogi® 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:

<b>Very common:</b>	<b>more than 1 of 10 patients treated</b>
<b>Common:</b>	<b>less than 1 of 10 but more than 1 of 100 patients treated</b>
<b>Uncommon:</b>	<b>less than 1 of 100 but more than 1 of 1,000 patients treated</b>
<b>Rare:</b>	<b>less than 1 of 1,000 but more than 1 of 10,000 patients treated</b>
<b>Very rare:</b>	<b>less than 1 of 10,000 patients treated, or unknown</b>

### 4.1 Possible side effects

Taking this drug may cause flatulence.

In individual cases 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.

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.

### 4.2 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® must not be taken for a further time.

### 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](http://www.bfarm.de). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Yomogi®

Keep out of the reach and sight of children.

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

### Storage conditions:

Do not store above 25 °C!

## 6. Further information

### 6.1 What Yomogi® contains

The active substance is:

1 hard capsule contains:

250 mg dry yeast of *Saccharomyces cerevisiae* HANSEN CBS 5926 (med. synonym: *Saccharomyces boulardii*) corresponding to min.  $2.5 \times 10^9$  viable cells.

The other ingredients are:

Lactose, magnesium stearate (Ph. Eur.), gelatine, purified water, sodium dodecyl sulfate, chlorophyllin-copper complex, titanium dioxide, iron oxide hydrate.

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

### 6.2 What Yomogi® looks like and contents of the pack

**Appearance:** Light-green / yellow hard capsules

#### Packs:

Yomogi® is available in the following packs:

10 hard capsules

20 hard capsules

50 hard capsules

100 hard capsules

### 6.3 Marketing authorisation holder and manufacturer

Ardeypharm GmbH, Loerfeldstr. 20, 58313 Herdecke, Germany

**This leaflet was last approved in December 2014.**

**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.**