

Yomogi®

Saccharomyces cerevisiae HANSEN CBS 5926 (Synonym: *Saccharomyces boulardii*)

What is in this leaflet

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

This leaflet answers some common questions about Yomogi®. It does not contain all the available information. It does not take the place of talking to your doctor, healthcare professional or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

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

You must contact your Doctor or healthcare professional if your symptoms worsen or do not improve.

If any of the side effects are serious, or if you notice any side effects not listed in this leaflet, please tell your Doctor or healthcare professional.

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

Pharmacotherapeutic group and mode of action

Yomogi® contains viable dry yeast from cultures of the defined strain *Saccharomyces cerevisiae* HANSEN CBS 5926 (synonym: *Saccharomyces boulardii*) and unfolds its effects in the intestine.

Yomogi® is used:

To maintain and support a healthy gastrointestinal immune system function.

Yomogi® helps maintain and support beneficial gut flora during and after antibiotic use.

Yomogi® can also help reduce and relieve diarrhoea in adults and children and the occurrence of diarrhoea. Yomogi® helps reduce the occurrence and relieves symptoms of traveller's diarrhoea.

2. BEFORE YOU TAKE YOMOGI®

Do not take Yomogi®

- If you are hypersensitive (allergic) to *Saccharomyces cerevisiae* HANSEN CBS 5926 (synonym: *Saccharomyces boulardii*) or any of the other ingredients of Yomogi®.
- If you are hypersensitive (allergic) to yeast.
- immunocompromised or hospitalised patients (due to serious illness or altered/weakened immune system)
- patients having a central venous catheter.

Saccharomyces cerevisiae HANSEN CBS 5926 is a living microorganism, which under inappropriate conditions, that occur in patients with an impaired immune defense system, may cause systemic fungal infections by migration from the intestinal tract in the blood or by external contamination of central venous catheter.

There have been very rare cases of fungemia (and blood cultures positive for *Saccharomyces* strains) and sepsis reported mostly in patients with central venous catheter, critically ill or immunocompromised patients, most often resulting in pyrexia. In most cases, the outcome has been satisfactory after cessation of treatment by *Saccharomyces boulardii*, administration of antifungal treatment and removal of the catheter when necessary. However, the outcome was fatal in some critically ill patients (see section 4. "Possible side effects").

In children:

No adequate 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.

Take special care with Yomogi®

With diarrhoea lasting longer than 2 days or accompanied by blood in the stool or a rise in temperature, you should consult a doctor.

If diarrhoea persist for more than 6 hours in infants under 6 months – 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice.

With diarrheal diseases, especially in children, attention must be paid to the use of fluid and electrolytes as

the most important therapeutic measure. Diarrhoea in children demands consulting the doctor.

If symptoms persist consult your doctor or healthcare professional.

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.

Taking other medicines

The concomitant administration 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.

Taking with food and drink

There are no interactions with food and drink.

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 medicine should not be used during pregnancy and lactation.

Driving and using machines

No special precautions are necessary.

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, pharmacist or Healthcare Professional has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage

Directions for use:

Adults and children from 2 years of age:

1 capsule 1-2 times daily

Children 2-6 years of age, open the hard capsule and stir contents into food or liquid.

Travellers' diarrhoea:

1 capsule 1-2 times daily starting 5 days before departure and continue for the duration of travel.

Antibiotic use: 1 capsule 1-2 times daily

Method of administration

Please take the hard capsules whole, swallow with an appropriate amount of fluid (preferably a glass of water) before meals. Do not chew.

In children from 2-6 years of age, the hard capsule can be opened by pulling it apart and the contents stirred into food or liquid (room temperature).

Duration of treatment

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

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.

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.

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.

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, healthcare professional or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Yomogi® can cause side effects, although not everybody will experience them.

If they occur, most are likely to be minor and temporary.

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

Very common:
affects more than 1 user
in 10

Common:
affects 1 to 10 users
in 100

Uncommon:
affects 1 to 10 users
in 1,000

Rare:
affects 1 to 10 users
in 10,000

Very rare:
affects less than 1 user
in 10,000

Not known:
frequency cannot be
estimated from the
available data

Possible side effects

Gastrointestinal disorders:

Taking this drug may cause flatulence.

Skin and subcutaneous disorders:

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.

Very rare: invasion of yeast into the bloodstream (fungemia).

Unknown frequencies side effects: Serious blood infection (sepsis).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet,

please tell your pharmacist.

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.

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!

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Yomogi® contains

– The active substance is: Dry yeast from *Saccharomyces cerevisiae* HANSEN CBS 5926 (synonym: *Saccharomyces boulardii*)

1 hard capsule contains:

Min. 2.5 billion viable cells of *Saccharomyces cerevisiae* HANSEN CBS 5926 (synonym: *Saccharomyces boulardii*) in 250 mg lyophilisate

The other ingredients are:

Lactose, magnesium stearate (Ph. Eur.), gelatin, 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.

What Yomogi® looks like and contents of the pack

Appearance

Light-green/yellow hard capsules

Packs

Yomogi® is available in the following packs:

20 hard capsules
50 hard capsules

Manufacturer and Australian sponsor

Ardeypharm GmbH
Loerfeldstr. 20
58313 Herdecke
Germany
Tel: +49 (0) 2330 977 677
Fax: +49 (0) 2330 977 697
www.ardeypharm.de

Australian sponsor:

Natural Therapy Imports
Suite 4, 74 Prospect Road
Prospect SA 5082
Tel: 01300 819 765
www.yomogi.com.au
ARTG Number:
AUST L 321332

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