

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 practitioner 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 practitioner 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 practitioner.

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 for

- the treatment of symptoms of diarrhoea.
- helps to reduce the occurrence of antibiotic associated diarrhoea.
- provides treatment of diarrhoea after antibiotic use.
- may reduce the risk and occurrence of traveler's diarrhoea.
- the prevention and treatment of symptoms of travelers' 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.

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.

Notice:

Due to the fact that the risk of a systemic colonization with *Saccharomyces cerevisiae* HANSEN CBS 5926 (synonym: *Saccharomyces boulardii*) is not assessable yet, 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.

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 practitioner.

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 risk during pregnancy and the lactation period.

However, there are no clinical studies on the safety of *Saccharomyces cerevisiae* during pregnancy. 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 practitioner has told. You should check with your doctor or pharmacist if you are not sure.

Dosage

Unless otherwise prescribed by your doctor or healthcare practitioner, the usual dose for children over the age of 2 and adults is:

For the treatment of diarrhoea, 1 hard capsule 1–2 times daily.

For prevention of travelers' diarrhoea, 1 hard capsule 1–2 times daily starting 5 days before the departure and continue for the duration of travel.

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 under 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 practitioner 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.

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.

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:

Store below 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. 250 x 10⁶ CFU 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

www.ardeypharm.de

Australian sponsor:

Natural Therapy Imports

Suite 4, 74 Prospect Road

Prospect SA 5082

Tel: 1300 819 765

www.yomogi.com.au

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