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. How­
ever, 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 prac­
titioner.

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 Saccha­
oromycetes cerevisiae HAN­SEN CBS 5926 (synonym: Saccharomycoses 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 diar­hoea 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 Saccharomycoses cerevisiae HANSEN CBS 5926 (synonym: Saccharomycoses 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 Saccharomycoses cere­visiae HANSEN CBS 5926 (synonym: Saccharomycoses 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 pressures.

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 Saccharomycoses 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 above­mentioned 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 10^6 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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