

NORMAGUT Capsules

Saccharomyces Boulardii 250mg

WHAT IS IN THIS LEAFLET

1. What NORMAGUT is used for
2. How NORMAGUT works
3. Before you use NORMAGUT
4. How to use NORMAGUT
5. While you are using NORMAGUT
6. Side effects
7. Storage and disposal of NORMAGUT
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

WHAT NORMAGUT IS USED FOR

NORMAGUT is indicated for

- Treatment of acute diarrhea in children and adults
- Prevention of antibiotic-associated diarrhea in children and adults
- Prevention of tube feeding associated diarrhea in adults.
- Addition to vancomycin / metronidazole treatment to prevent recurrence of Clostridium difficile diseases in adults.

HOW NORMAGUT WORKS

Saccharomyces boulardii is an intestinal replacement flora (live probiotic yeast) which acts as antidiarrheal microorganisms in the digestive tract. Saccharomyces boulardii protects the digestive tract against pathogens and restore normal flora.

BEFORE YOU USE NORMAGUT

- When you must not use it

- Hypersensitivity to one of the components
- Patients with central venous catheter
- Critically ill patients or immunocompromised patients due to a risk of fungaemia.

- Pregnancy and Lactation

Saccharomyces boulardii is not recommended due to lack of sufficient data for the safe use during pregnancy and breast feeding.

- Before you start to use it

- Consult your doctor or pharmacist if you are critically ill / immunocompromised

- Taking other medicines

- Inform your doctor if you are taking antifungal medicine or any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

HOW TO USE NORMAGUT

- How much to use

Children (> 6 years old): 1 to 2 capsules daily.

Adults: 1 or 2 capsules, once or twice daily. Capsules should be swallowed with a glass of water.

The capsules can be taken either during, before or after meals. For children below 6 years old (who are unable to swallow), discard the capsule shell & empty the contents into a feeding bottle or a glass of water/juice.

- How long to use it

-Treatment of acute infectious diarrhoea of children and adults: approximately 1 week.

-Prevention of antibiotic-associated diarrhoea in children and adults: treatment should be started within 48 to 72 hours of the beginning of treatment with antibiotics and it should continue for at least three days and not longer than 4 weeks after the treatment with antibiotics is ended.

-Addition to vancomycin/metronidazole-treatment to prevent recurrence of Clostridium difficile diseases in adults: treatment should be started as soon possible after the beginning of antibiotic treatment and it should continue for 4 weeks.

-Prevention of tube-feeding associated diarrhoea in adults: during the period of tube-feeding.

The maximum duration of treatment is 4 weeks.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE USING NORMAGUT

- Things you must do

While taking NORMAGUT, make sure to do the following:

- Drink sufficient liquid including salted or sweetened drinks to compensate for the loss of liquid due to the diarrhea. Adults are recommended to drink 2 liters of water a day.
- Eat by privileging roasted meats and rice during the diarrhea but avoid fruits, green vegetables, spiced dishes, food or frozen drinks.
- In case of doubt, do not hesitate to seek the advice of your doctor or your pharmacist.
You must consult your doctor immediately in the following cases:
- Do not see any improvement after 2 days of treatment.
- In case of fever, vomiting.
- In case of presence of blood or mucus in the stools.
- In case of intense thirst, dryness of tongue: these signs show the beginning of the dehydration, that means an important loss of liquid due to the diarrhea. Your doctor will decide the necessity to prescribe a rehydration.
- You become pregnant while taking this medication.

- Things you must not do

Do not take NORMAGUT with very hot (over 50°C), iced or alcoholic drinks or food.

Do not take any new medicines without consulting your doctor.

Do not give NORMAGUT to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Check with your doctor or pharmacist.

SIDE EFFECTS

Infections and Infestations

Very rare: Fungaemia in patients with a central venous catheter and in critical ill or immunocompromised patients. May often cause flatulence.

Normagut can cause side effects to gastro intestine (flatulence), skin (rash, cutaneous allergy, urticarial, pruritus), immune system (allergic response including swelling below the skin surfaces and breathing difficulties).

- Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.
- You may report any side effects or adverse drug reactions to the National Centre for Adverse Drug Reaction Monitoring or visiting the website npra.gov.my (Consumers → Reporting)

STORAGE AND DISPOSAL OF NORMAGUT

- Storage

Store below 30°C in a dry place, away from direct sunlight.

- Disposal

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

PRODUCT DESCRIPTION

- What it looks like

Capsule appearance/shape: Elongated, shiny, opaque hard gelatine capsules with light green body and yellow cap. Capsule Size 1.

Appearance of capsule content: ochre to beige-grey coloured, granular powder with a characteristic smell.

- Ingredients

-Active ingredient

Each capsule contains 250 mg of *Saccharomyces boulardii*.

- MAL number

MAL xxxxxxxxxxxx

MANUFACTURER

ARDEYPHARM GMBH

Loerfeldstrasse 20, 58313

Herdecke, Germany.

PRODUCT REGISTRATION HOLDER

MEGA LIFESCIENCES SDN.

BHD.

B-28-02, The Ascent, Paradigm, No.1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia.

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