

NORMAGUT SACHETS

Saccharomyces boulardii (250mg)

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WHAT NORMAGUT IS USED FOR

NORMAGUT is indicated for acute diarrhoea in infants, children and adults; prevention of antibiotic-associated diarrhoea in children and adults; prevention of recurrence of *Clostridium difficile* in adults and prevention of diarrhoea during continuous enteral tube feeding 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 restores 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 breastfeeding.

- Before you start to use it

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

- Taking other medicines

Tell your doctor if you are taking 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

Infants and children: 1 or 2 sachets daily.
Adults: 1 or 2 sachets, once or twice daily.

The sachets can be taken either during, before or after meals. Pour the contents of the sachet in a glass of water or sweetened beverage, mix, and drink. The powder can also be mixed with food or poured into a baby's feeding-bottle.

NORMAGUT contains living cells. This product should therefore not be mixed with very hot (over 50°C), iced or alcoholic drinks or food.

- How long to use it

- Treatment of acute infectious diarrhoea of infants, 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 in the usual indications 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 diarrhoea. Adults are recommended to drink 2 litres of water a day.
- Eat by privileging roasted meats and rice during the diarrhoea 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 diarrhoea. 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.

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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 directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

STORAGE AND DISPOSAL OF NORMAGUT

- Storage

Store below 30°C in a dry place, away from direct sunlight. Keep out of the reach of children.

- Disposal

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.

PRODUCT DESCRIPTION

- What it looks like

Aluminium sachets containing free flowing, off-white to light brown powder with a fruity flavour and odour.

- Ingredients

- Active ingredient:

Each Sachet Contains:

Freeze-dried yeast of *Saccharomyces boulardii* 250 mg
(*Saccharomyces cerevisiae* HANSEN CBS 5926)

- Inactive ingredients:

Fructose, colloidal anhydrous silica, fruity flavor.

- MAL number

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MANUFACTURER

MEGA LIFESCIENCES
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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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23/10/2025

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