

BIOMICTRA FAECAL MICROBIOTA TRANSPLANT (FMT)

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor.

1. Why am I being given BIOMICTRA FAECAL MICROBIOTA?

BIOMICTRA is used to deliver bacteria derived from screened donor faeces into the bowel of a patient with the aim of treating disease by replenishing gut bacterial diversity. BIOMICTRA contains the active ingredient faecal microbiota.

For more information, see Section [1. Why am I using BIOMICTRA?](#) in the full CMI.

2. What should I know before I am given BIOMICTRA FAECAL MICROBIOTA?

Do not use if you have an anaphylactic food allergy or ever had an allergic reaction to any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use BIOMICTRA?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given BIOMICTRA FAECAL MICROBIOTA?

BIOMICTRA FAECAL MICROBIOTA can be introduced into the bowel by your doctor, either via colonoscopy, enema, endoscopy or a thin tube that is passed through the nose and into the stomach or small bowel (nasogastric or nasoenteric tube).

More instructions can be found in Section [4. How will I be given BIOMICTRA?](#) in the full CMI.

5. What should I know while being given BIOMICTRA FAECAL MICROBIOTA?

Things you should do	• If you experience any problems during your treatment, tell your doctor. • If you become pregnant whilst receiving FMT, tell your doctor immediately
Driving or using machines	• Do not drive or operate machinery after your colonoscopy if you have been administered sedation or an anesthetic

For more information, see Section [5. What should I know while being given BIOMICTRA FAECAL MICROBIOTA?](#) in the full CMI.

6. Are there any side effects?

Some common side effects of BIOMICTRA FAECAL MICROBIOTA include transient symptoms of abdominal bloating, discomfort or diarrhoea.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

BIOMICTRA™ FAECAL MICROBIOTA TRANSPLANT (FMT)

Active ingredient(s): 12.5 g *Faecal microbiota*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BIOMICTRA. **You should also speak to your doctor if you would like further information or if you have any concerns or questions about using BIOMICTRA.**

Where to find information in this leaflet:

- [1. Why am I being given BIOMICTRA?](#)
- [2. What should I know before I am given BIOMICTRA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given BIOMICTRA?](#)
- [5. What should I know while being given BIOMICTRA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given BIOMICTRA?

BIOMICTRA FAECAL MICROBIOTA is used for the restoration of the gut microbiota which are the healthy associated microorganisms that live in your gut.

BIOMICTRA contains the active ingredient **Faecal microbiota from a screened donor**. BIOMICTRA FAECAL MICROBIOTA is only available when prescribed by a doctor. BIOMICTRA FAECAL MICROBIOTA involves the delivery of bacteria derived from screened donor faeces into the bowel of a patient with the aim of treating disease. The FMT can be introduced into the bowel by either enema, a colonoscopy, or a thin tube that is passed through the nose and into the stomach or small bowel. Faecal donors are anonymous healthy volunteers. Donors are thoroughly screened for infection or any potentially transmissible disease, similar to how blood donation is conducted in the community. Following screening, donor stool is frozen for use at a later date.

What should I know before I am given BIOMICTRA?

Warnings

Do not use BIOMICTRA if you have:

- Anaphylactic food allergy.** BIOMICTRA contains food antigens from the donor's diet and so could induce anaphylaxis in a recipient who was susceptible
- Allergy** to any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- Suspected bowel perforation

Check with your doctor if you:

- If you have any allergies to medicines, chemicals or foods
- If you are not sure whether you should have an FMT, talk to your doctor. Your doctor can discuss the risks and benefits involved.

During treatment, you may be at risk of developing certain side effects. It is important that you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant whilst receiving FMT.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children and adolescents

There is very limited data on the use of FMT in children and adolescents. You should discuss the use of FMT with your paediatrician.

Severe illness and immunodeficiency

The risks of FMT may be greater in some patients who have severe underlying health conditions or have a very depleted immune system. The risks and benefits of FMT in this setting should be discussed with your doctor.

Preparation Prior to BIOMICTRA FAECAL MICROBIOTA

- Your doctor will advise as to the appropriate preparation prior to BIOMICTRA FAECAL MICROBIOTA and this will vary depending on disease indication.
- You may also be provided with a standard information sheet on colonoscopy (or other delivery procedure) from your hospital.

2. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BIOMICTRA.

3. How will I be given BIOMICTRA?

- BIOMICTRA FAECAL MICROBIOTA can be introduced into the bowel by your doctor, either via colonoscopy, enema, endoscopy or a thin tube that is passed through the nose and into the stomach or small bowel (nasogastric or nasoenteric tube).
- Speak to your doctor as to the most appropriate method of FMT delivery for you
- The amount of FMT given is at the discretion of your treating doctor. The usual dose of FMT is 200 mL when administered by colonoscopy, or 50 mL when given via enema or nasogastric/nasoenteric tube.
- Your doctor will check your response to FMT therapy. Depending on how you respond to therapy, your doctor will decide whether further doses of FMT are required.
- Follow the instructions given by your doctor carefully.
- If you do not understand the instructions, ask your doctor for help.
- It is important to see your doctor regularly when receiving FMT therapy.
- Your doctor will decide when you will be given FMT.
- Your doctor will decide how many doses of FMT you will require and over what time period.

4. What should I know while being given BIOMICTRA?

Things you should do

- If you experience any problems during your treatment, tell your doctor.
- Tell your doctor immediately if you develop abdominal pain, changes in your bowel habit, fever, or any other symptom that concerns you.
- If you become pregnant whilst receiving FMT, tell your doctor immediately

Things you should not do

- **Do not drive or operate machinery after your procedure if you have been administered sedation or an anesthetic**

Looking after your medicine

- BIOMICTRA FAECAL MICROBIOTA is stored at -80°C by your treating doctor according to product instructions

When to discard your medicine

- Each FMT syringe is single use and is to be discarded following use

5. Are there any side effects?

All medicines can have side effects. The most common side effects with FMT are minor and temporary. However,

some side effects may be serious and require medical attention.

See the information below and, if you need to, ask your doctor if you have any further questions.

Less serious side effects

Less serious side effects	What to do
• Abdominal symptoms such as bloating or pain/discomfort • Nausea or vomiting • Diarrhoea • Post infectious irritable bowel syndrome	Speak to your doctor if you have any of these side effects and they worry you.

Serious/rare side effects of FMT

Serious side effects	What to do
• Fever • Diverticulitis • Infection or sepsis • Immune-related disease • Treatment failure • Relapse of condition • Allergic reactions such as rash, lip/tongue swelling, difficulty breathing	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effect.

Serious/rare side effects of Colonoscopy

Serious side effects	What to do
• Bowel perforation • Dehydration from bowel preparation • Over sedation • Aspiration • Bleeding • Splenic laceration	Call your doctor immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor if you notice anything else that may be making you feel unwell.

There is an association between some medical conditions such as obesity and certain gut bacterial profiles. It is for this reason we rigorously screen donors for any medical conditions that could potentially impact on the FMT recipient. **Tell your doctor immediately if you have any concerns that you have acquired another condition following FMT.** This may include changes in your weight, mood, joint and/or muscle aches/inflammation, frequency of urination or any other new symptom of concern.

There have been a small number of deaths associated with FMT in many thousands of cases and the risk of this is very low. There has been at least one recorded case of a patient dying from a drug resistant infection transferred via FMT, however BiomeBank screens for this and other drug resistant infections so the risk of this occurring is low.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

6. Product details

What BIOMICTRA contains

Active ingredient	12.5 g faecal microbiota
Other ingredients	Sodium chloride 0.9% (32.5 mL) Glycerol (5 mL)

Do not receive this medicine if you are allergic to any of these ingredients.

What BIOMICTRA looks like

The BIOMICTRA FAECAL MICROBIOTA syringe contains 50 mL of brown-coloured suspension

ARTG: 399066

Who distributes BIOMICTRA?

BiomeBank

2 Ann Nelson Drive

Thebarton SA 5031

Australia

<https://biomebank.com>

This leaflet was prepared in March 2022