

## Patient Information Leaflet - FMT

### What is a Faecal Microbiota Transplant (FMT)?

Faecal microbiota transplants aim to restore a healthy balance of bacteria in the gut of people who have recurrent *Clostridium difficile* (rCDI) infections by introducing intestinal bacteria from the faeces of healthy donors.

### How is FMT performed?

Healthy donors are screened for bacterial pathogens, viruses and parasites. Donor faeces are diluted and filtered to remove large particles. This is then stored frozen before being shipped to a requesting clinician for use. The resulting suspension is frozen and shipped to a requesting clinician for use. It is thawed and introduced into the recipient's gut either via a nasogastric tube, nasoduodenal tube, rectal enema or via the biopsy channel of a colonoscope.

### Is the EnteroBiotix product safe?

To date, there has not been any documented cases of infection transmitted through a faecal transplant. That being said, faeces are a "bodily fluid" and although EnteroBiotix implements rigorous donor screening and testing procedures including donor health questionnaires, health screening and routine blood and stool tests, a risk potentially exists for the transmission of biological agents and microbiologically uncharacterised material.

EnteroBiotix is compliant with the Medicines and Healthcare products Regulatory Agency (MHRA) requirements, comply with Good Manufacturing Practice (GMP) and are authorised by the MHRA to manufacture frozen faecal microbiota as an unlicensed or "Specials" medicinal product which are only issued on a named patient basis through your clinician or healthcare professional.

### Is the FMT procedure safe?

Your healthcare professional should explain what is involved in having the FMT procedure and discuss the possible benefits and risks with you. Known side effects include:

- Belching - common
- abdominal cramps - common

- abdominal pain - common
- diarrhoea – very common
- constipation during follow up - common

You will be asked to sign a consent form acknowledging the risks of undergoing FMT as well as theoretical risks related to the faecal transplant itself.

### How successful is FMT?

As this treatment is still developing, data is still emerging about the efficacy and success of FMT. However, a recent systematic review reported that across seven randomised controlled trials (RCT's), FMT cured 95% of patients suffering from recurrent CDI. In contrast, antibiotics cured on average around 30% of patients.

The National Institute for Health and Care Excellence (NICE) issued guidance to the National Health Service (NHS) in England, Wales, Scotland and Northern Ireland on FMT for rCDI. They state that the current evidence on the efficacy and safety of FMT for rCDI infection is adequate to support the use of the procedure provided that normal arrangements are in place for clinical governance, consent and audit.

### Faecal Microbiota Transplant - Responsibility

The guidance noted above represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of you the patient, in consultation with you and/or guardian or carer.

### Reporting Side Effects

If you experience any serious side effects, you must talk to your doctor immediately. If necessary you can report any serious or adverse events associated with your treatment directly to the MHRA via the yellow card system <https://yellowcard.mhra.gov.uk/> and using the EnteroBiotix Serious Adverse Reaction/Event form (FRM EUR 024).