MICROBIOME BANK LTD.
2 Brandon Road
Braintree, Essex, UK
CM7 2NL

AUTOBIOME

Service Datasheet

For healthcare professionals

Autologous (self-derived) lyophilized microbiota transplantation (aMTT) graft capsule for storing and later restoring one's own healthy gut flora

MicroBiome Bank

v1.0 — 2026-08-15

This document is the official datasheet of the AutoBiome service: a complete description approved by MicroBiome Bank Ltd. It is addressed to healthcare professionals, ordering institutions and patients seeking information. It is not a treatment instruction, it does not replace the treating physician's individual judgement, and it does not constitute a medicinal product summary of product characteristics.

CONFIDENTIAL — FOR HEALTHCARE PROFESSIONALS ONLY

Document details

Version	Status	Approved by	Approval timestamp
1.0	Approved	Dr. Patay Gábor	2026-08-15 08:00

What is this document about? The document presents the AutoBiome service in nine chapters. Chapters I–II cover the service name, its variations and description, together with the indications, the active substance and the mechanism of action. Chapter III details the method of use, the packaging, the storage conditions, the dosage, the tapering protocol and the stool collection procedure. Chapters IV–V summarise the advantages, the pricing, the quantity discounts and the available product bundles. Chapter VI addresses donor screening, drug interactions, known side effects and precautions, while Chapter VII describes the manufacturing process and quality control from pathogen screening to batch documentation. Chapters VIII–IX set out the considerations for special populations, the regulatory classification, the conditions of prescribing and dispensing, and the reporting obligations.

Unique document identifier:

DS-AUTOBIOME-EN-v1.0-202608150800

Contents

I. Name of Product, General Information 4
- I.1 Name of Product 4
- I.2 Full Name of Product 4
- I.3 Product variations 4
- I.4 Description 4

II. Scope of Use, Active Ingredients, Mechanism of Action 4
- II.1 Indications 4
- II.2 Active Substance 4
- II.3 Mechanism of action 4

III. Method of Use, Packaging, Storage, Dosage and Tapering 4
- III.1 Method of use 4
- III.2 Packaging 5
- III.3 Storage 5
- III.4 Dosage 5
- III.5 Tapering 6
- III.6 Stool Collection Procedure 6

IV. Advantages 6
- IV.1 Non-Invasive Delivery 6
- IV.2 Autolog therapy 6
- IV.3 Preventive and Restorative Therapy 6
- IV.4 Convenience 6

V. Pricing, Quantity Discounts, and Packaging Options 6
- V.1 Pricing 6
- V.2 Quantity Discounts 6
- V.3 Product Bundles 7

VI. Additional Information 7
- VI.1 Donor Screening and Safety 7
- VI.2 Drug Interactions 7
- VI.3 Known Side Effects 7
- VI.4 Warnings and Precautions 7

VII. Manufacturing Process and Quality Control 7
- VII.1 Microbiological Testing of the Donated Stool (Donatum) 7
- VII.2 Processing and Formulation 8
- VII.3 Excipients and Vitalization Additives 8
- VII.4 Batch (LOT) Identification and Documentation 8
- VII.5 Microbiological Testing and Contaminant Exclusion 8
- VII.6 Excipients and Additional Components 8
- VII.7 Ongoing Quality Oversight 8

VIII. Special Populations 9
- VIII.1 Elderly Patients 9
- VIII.2 Pediatric Use 9

IX. Additional Considerations and Regulatory Status 9

IX.1 Regulatory Classification 9
IX.2 Prescribing and Dispensing 9
IX.3 Pharmacovigilance and Reporting 9

I. Name of Product, General Information

I.1 Name of Product

AutoBiome

I.2 Full Name of Product

AutoBiome – Autologous (self-derived) microbiota transplantation (aMTT) capsule

I.3 Product variations

Within the framework of the AutoBiome therapeutic service, the capsules are provided in units of 60 each. The standard order quantity is 6× 60 capsules (a total of 360). The exact packaging configuration may vary depending on ordering options and clinical protocols. As needed, the patient and the physician can jointly determine the number of capsules required for future use.

I.4 Description

AutoBiome is an orally administered autologous microbiota transplantation (aMTT) formulation that allows an individual's earlier, healthy gut microbiota to be collected and stored for future restoration if needed. The stool sample is obtained when the person is younger or in an ideal state of health, then freeze-dried and encapsulated before being returned to the patient. This approach offers the most personalized and safest way to restore one's own gut flora.

II. Scope of Use, Active Ingredients, Mechanism of Action

II.1 Indications

The use of AutoBiome is recommended for individuals who are otherwise in excellent health but anticipate medical interventions, treatments, or lifestyle factors (e.g., extended antibiotic therapy, oncological or surgical procedures, travel to "exotic" countries, high-risk professions, athletic performance scheduling, etc.) that may disrupt gut microbiota balance. It is crucial for the patient to have a healthy microbiota at the time of sample collection, so that later on they can benefit from their own guaranteed-compatible preparation, enabling a faster and more assured recovery.

II.2 Active Substance

The active substance in AutoBiome is the individual's own previously collected, healthy colon-derived microbiota suspension in freeze-dried form. During the transformation, strict quality and safety standards are followed to ensure that the material used for microbiota transplantation meets all health requirements valid at the time of the patient's sample collection. This autolog solution not only avoids donor-recipient compatibility issues but also optimally supports the restoration of gut microbiota balance during future therapeutic interventions.

II.3 Mechanism of action

The active component of AutoBiome is the individual's own previously collected and freeze-dried healthy gut microbiota concentrate. Once taken orally, these live microorganisms recolonize the patient's gastrointestinal tract, restoring natural microbial diversity and balance.

III. Method of Use, Packaging, Storage, Dosage and Tapering

III.1 Method of use

- Oral administration: AutoBiome capsules should primarily be taken orally without chewing or opening them, preferably on an empty stomach and with plenty of water. Thirty minutes after taking the capsules, drink additional fluids to maintain proper hydration and ensure optimal colonization

conditions. After this period, other medications can be taken, and normal daily activities may be resumed.

- Timing: capsules should be taken first thing in the morning. Avoid simultaneous consumption with alcoholic beverages or hot liquids.

III.2 Packaging

Dark Glass Containers: AutoBiome capsules are supplied in dark glass bottles to ensure effective protection from light and maintain quality. This packaging is designed to preserve the viability of the microorganisms and ensure consistent therapeutic efficacy throughout the treatment period.

Each bottle contains 60 capsules, representing the 30 day dose referred to as the packaging unit. To support typical treatment protocols, a single glass container is adequate to cover the entire treatment period for one patient.

The standard treatment package contains 6 packaging units (6 × 60 capsules), which is sufficient for six complete treatment periods.

- Moisture and Contaminant Control
- Tamper-Evident Seal: each container is equipped with a tamper-evident closure to safeguard capsule integrity and ensure they remain uncompromised.

Child-Resistant Closure: in compliance with local regulations, a child-resistant cap may be included to enhance safety and prevent unauthorized access. The preparation you ordered is equipped with a child-resistant closure if it is required by the regulations in your country.

- Labeling
- The label clearly displays the service name, the number of capsules, the batch number, the expiration date and storage instructions for clear reference.
- It includes a designated area for healthcare providers or pharmacists to record the dispensing date if required.

III.3 Storage

Room Temperature (up to 25°C / 77°F): a transport and transitional tolerance, not a mode of storage. Store in the unopened, original packaging. The capsules remain stable for up to 6 months (180 days) when kept away from excessive heat and direct sunlight. The capsule is not damaged by brief periods at room temperature, but its place of storage is the refrigerator.

- Refrigerated (+4°C to +8°C / 39–46°F): when stored in a sealed, dark glass container, the capsules are stable for up to 24 months.
- Deep Freeze (below –20°C / –4°F): properly sealed and protected from light, the capsules can be stored for up to 20 years.

Handling Recommendations:

- Ensure the container is tightly closed when not in use.
- Store in an upright position to reduce the risk of capsule damage.
- Minimize frequent opening and closing, as this may alter humidity levels inside the container.

III.4 Dosage

- Standard Treatment Course: the recommended regimen involves taking 2 capsules daily for a specified duration, typically around 15 days, depending on the treatment protocol.
- Physician's Discretion: the exact dosage and duration should be determined by the treating physician, customized to the patient's clinical status, medical history, and tolerance.

III.5 Tapering

The pace of dose reduction is set by the patient's condition, not by a suggested schedule.

- Sequential Reduction: in specific cases, such as frequent recurrences, a step-down protocol may be employed, where the initial daily dose is gradually decreased over time.
- Clinical Monitoring: patients should be closely observed during the tapering process for any signs of symptom recurrence or adverse reactions.
- Follow-Up: A post-treatment follow-up, typically conducted within 1–2 weeks after the final dose, is recommended to evaluate therapeutic outcomes and ensure patient recovery.

III.6 Stool Collection Procedure

For the AutoBiome service, the patient must use the included AutoBiome Stool Collection Kit to collect their own stool sample. The documentation provided with the kit offers detailed instructions on correct stool collection. It is important that, during sample collection, the stool does not come into contact with water, urine, or any other foreign substances, and that it is gathered according to the specified protocol. The sample must then arrive at the laboratory by courier in compliance with the outlined guidelines.

IV. Advantages

IV.1 Non-Invasive Delivery

Oral capsule administration provides a minimally invasive alternative to traditional MTT methods, such as colonoscopy or enema, reducing both patient discomfort and procedural risks.

IV.2 Autolog therapy

AutoBiome is designed to preserve the patient's own healthy microbiota, thereby eliminating any potential donor-recipient compatibility issues.

IV.3 Preventive and Restorative Therapy

Using these capsules, the patient can "preserve" a state of health that later—during potential medical interventions, unexpected infectious diseases, or exposure to unusual (foreign) environmental microbes —allows for the restoration of the original, healthy microbiota.

IV.4 Convenience

Oral capsules are easy to store and administer, making them suitable for outpatient settings. This reduces logistical challenges for healthcare facilities and decreases dependence on specialized procedures. The capsule form significantly enhances patient adherence to therapy.

V. Pricing, Quantity Discounts, and Packaging Options

V.1 Pricing

The final price of AutoBiome may vary depending on agreements with intermediary healthcare institutions and local regulations.

V.2 Quantity Discounts

For large orders placed by police, military, or other organizations exposed to heightened health risks, quantity discounts can be offered, thus reducing both procurement and future treatment costs.

V.3 Product Bundles

Depending on the dry matter content of the provided donor material, AutoBiome can be ordered in a minimum quantity of 6 × 60 capsules (six packaging units), which can be sufficient for up to six complete treatment courses, depending on the health issue being addressed.

VI. Additional Information

VI.1 Donor Screening and Safety

Rigorous Screening: in this case, the donor and the recipient are the same individual. The human microbiota obtained from the patient undergoes thorough screening in accordance with relevant guidelines (e.g., EMA, WGO, EAGEN, or local health authority regulations).

Comprehensive Testing: stringent microbiological, serological, and parasitological tests are performed to ensure the absence of infectious pathogens.

Quality Assurance: the GMP-compliant manufacturing process includes multiple quality control checkpoints to ensure consistency and safety of AutoBiome.

VI.2 Drug Interactions

Antibiotics: concurrent antibiotic use may diminish the efficacy of AutoBiome. Administration of the antibiotic must be completed at least 48 hours before the start of the course. Antibiotic treatment started during the therapy warrants suspension of the course. Alongside antibiotics it may be administered only in a life-threatening situation, following prior consultation and at an increased dose.

Probiotics: probiotics are to be discontinued during the course, unless the treating physician orders otherwise.

VI.3 Known Side Effects

Common and Mild: gastrointestinal discomfort, bloating, flatulence, diarrhea, or constipation. These effects are usually temporary and resolve without medical intervention.

VI.4 Warnings and Precautions

Immunocompromised Patients: patients with severe immunodeficiency or those on immunosuppressive therapy require close monitoring during MTT due to a higher risk of infection.

Pregnancy and Lactation: limited data is available; treatment should only be initiated after careful assessment by a healthcare provider.

Other Contraindications: patients with severe active gastrointestinal conditions (e.g., toxic megacolon, fulminant colitis) or suspected bloodstream infections should undergo thorough evaluation before initiating AutoBiome therapy.

VII. Manufacturing Process and Quality Control

VII.1 Microbiological Testing of the Donated Stool (Donatum)

Pathogen Screening: donated stool (“donatum”) is analyzed using multiplex PCR or conventional microbiological methods to detect enteric pathogens, including:

Salmonella, *Shigella*, *Yersinia*, *Campylobacter*

- Enteropathogenic *E. coli* (EAEC, EPEC, ETEC, STEC, EIEC)
- *Clostridioides* species
- *Plesiomonas*, *Vibrio*
- *Cryptosporidium*, *Cyclospora*, *Entamoeba histolytica*, *Giardia lamblia*

- Adenovirus, Astrovirus, Norovirus, Rotavirus, Sapovirus, SARS-CoV-2
- *Helicobacter pylori*
- Multidrug-resistant organisms (MRSA, MRSE, VRE, ESBL, CRE)
- Results: only donor samples confirmed to be free of the specified pathogens will be utilized in the final formulation of AutoBiome capsules.

VII.2 Processing and Formulation

After pathogen clearance, donor stool is processed into a bacterial suspension, lyophilized, and encapsulated using specialized pharmaceutical techniques to ensure microorganism viability and stability.

VII.3 Excipients and Vitalization Additives

To ensure optimal bacterial viability and support manufacturing integrity, each capsule contains:

- Amylum solani (potato starch)
- Inulin (chicory-derived)
- Pyridoxal 5'-phosphate (vitamin B6)
- Cyanocobalamin (vitamin B12)
- Pteroil-monoglutamic acid (folic acid, vitamin B9)

These components have been selected to promote microbial stability, bacterial viability during storage, and ensure patient safety.

VII.4 Batch (LOT) Identification and Documentation

- Each production batch is assigned a unique identifier tracking all related manufacturing data, including donor information, date of production, and raw material usage.
- Mandatory tests (e.g., microbiological purity checks, viable bacterial counts and active substance content) are performed according to predefined specifications prior to release.

VII.5 Microbiological Testing and Contaminant Exclusion

Regular microbiological screening (e.g., conventional culture methods, multiplex PCR) ensures the absence of contaminants or unintended pathogens.

- While the product is not manufactured under sterile conditions—given it contains live bacteria—a strict exclusion protocol is in place to rule out critical pathogens.
- Testing protocols follow strict local and international guidelines (e.g., EMA, WGO, EAGEN) for microbiological quality in biological products.

VII.6 Excipients and Additional Components

All excipients (e.g., Amylum solani [potato starch], inulin) and vitamin additives (B6, B12, folic acid) undergo rigorous quality checks to confirm purity, identity, and the absence of undesirable contaminants (e.g., heavy metals, residual solvents).

Certificates of Analysis (CoA) from suppliers may be required, and spot checks or additional in-house testing can be performed to verify compliance with the relevant pharmacopeial or internal specifications.

VII.7 Ongoing Quality Oversight

Any deviations or out-of-specification (OOS) results are thoroughly investigated, and corrective actions are implemented to maintain product integrity and regulatory compliance.

VIII. Special Populations

VIII.1 Elderly Patients

- Due to the potential for multiple comorbidities and concurrent medication use, AutoBiome should be used with caution in elderly patients, accompanied by closer monitoring for any adverse effects or interactions.

VIII.2 Pediatric Use

- Currently, there are no known conditions related to the use of AutoBiome capsules that would contraindicate the application of MTT in children under 18 years of age.

IX. Additional Considerations and Regulatory Status

IX.1 Regulatory Classification

AutoBiome is classified as a Medical Laboratory Services (869015). The finalisation of its classification by the EU regulatory authorities is in progress.

IX.2 Prescribing and Dispensing

AutoBiome should only be used under the supervision of a qualified healthcare professional. Its use may require compliance with specific protocols or special authorization, depending on regional and national regulations.

IX.3 Pharmacovigilance and Reporting

Any suspected adverse reactions must be reported to the relevant health authority (e.g., FDA, EMA, or local regulatory agencies) in line with applicable national regulations.

Note: This datasheet is provided for informational purposes and is intended for healthcare professionals and patients. Always seek advice from a healthcare professional before starting any new treatment.

Please note that MicroBiome Bank does not sell a product but facilitates the connection between donors and recipients by providing professional medical services. In accordance with applicable regulations, the capsules are provided as a service under code 869015 — Medical Laboratory Services, as defined by SCPA 2008. We handle donor recruitment, screening, fecal testing and the processing of the screened donation into capsule form through qualified laboratories. The contents of the capsules remain the property of the donor, subject to the cost of medical services, until fully paid by the recipient. The brand names of the individual services are intended solely to make them easier to remember and to simplify the ordering process.