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

SERVICE OVERVIEW

FOR ULTRABIOME MTT CAPSULES

1. Service Overview, General Information

1.1 Name of Service

UltraBiome

1.2 Full Name of Service

UltraBiome standardized intestinal microbiota graft for MTT

1.3 Service variations

UltraBiome 30(XX) and UltraBiome 30(L): The Arabic numeral (30) indicates the number of capsules in each package, while the Roman numeral (XX or L) represents the dosage level, derived from the dry matter content of the lyophilized material.

1.4 Description

UltraBiome is an orally administered human microbiota transplantation (MT) service specifically developed to support enhanced physical performance—whether you are starting a new exercise regimen or continuing at a higher intensity. The formulation is based on a carefully screened bacterial mass derived from ultra athletes, contributing over the long term to maintaining a balanced gut flora. This helps optimize metabolic and energy-producing processes, especially during exercise in the second performance zone.

UltraBiome is provided exclusively to patients who have successfully completed the necessary medical examinations. Manufactured under stringent safety and efficacy standards, it provides a dependable and effective solution for microbiota transfer therapy (MTT). As a result, patients have the opportunity to make lifestyle changes—particularly to begin or intensify regular physical activity—supporting better physical endurance and overall well-being.

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

2.1 Indications

UltraBiome is recommended for individuals seeking to boost their physical performance capacity and enhance their training efforts and endurance. If needed, UltraBiome can be re-administered using the selected batch (LOT) number as a “booster” therapy, supporting the continuous achievement and maintenance of training goals.

2.2 Active Substance

UltraBiome’s biologically active component is derived from strictly controlled human donor material originating from ultra athletes, specifically developed to enhance physical performance and endurance. Its main component is a standardized suspension of human colon-derived microbiota in a lyophilized form. UltraBiome capsules contain a high number of bacterial strains that support physical performance and fat burning. Production adheres to rigorous quality and safety standards, thereby ensuring the preparation’s high efficacy and safety.

2.3 Mechanism of action

UltraBiome exerts its therapeutic effect through a special “flooding” protocol, which involves daily capsule intake over a specified period (e.g., six consecutive months). Each capsule contains a carefully screened community of live gut microbes sourced from ultra-athletes. With prolonged use, these microorganisms gradually colonize the patient’s gastrointestinal tract, thereby altering the original gut flora. Upon successful colonization, UltraBiome helps establish a gut flora composition that resembles the microbial profile characteristic of ultra-athletes. As a result, the recipient’s physical

performance and endurance can increase significantly by raising the lactate threshold. Additionally, the formulation supports the more efficient breakdown of inflammation-inducing compounds, promotes intestinal wall regeneration, and aids in optimal nutrient utilization. The resulting higher microbial diversity and stability are essential for maintaining intestinal homeostasis and may reduce the risks associated with dysbiosis.

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

3.1 Method of use

- **Oral Administration**: UltraBiome capsules should primarily be taken orally without chewing or opening them, on an empty stomach, accompanied by plenty of fluids. Thirty minutes after taking the capsules, additional fluids should be consumed to ensure proper hydration and optimal absorption. Following this, other medications can be taken, and the regular daily routine may resume.
- **Timing:** capsules should be taken first thing in the morning. Avoid simultaneous consumption with alcoholic beverages or hot liquids.

3.2 Packaging

- Dark Glass Containers: UltraBiome capsules are packaged 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 30 capsules, representing the 30 day dose referred to as the packaging unit. The exact procedure for using the UltraBiome protocol is determined by the attending physician or sports medicine specialist.**
- Moisture and Contaminant Control
    - Tamper-Evident Seal: Each container is equipped with a tamper-evident closure to safeguard product integrity and ensure it remains uncompromised.
    - Child-Resistant Closure: In compliance with local regulations, a child-resistant cap may be included to enhance safety and prevent unauthorized access. The product 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 product name, the number of capsules, the batch number, the expiration date and storage instructions for easy reference.
    - It includes a designated area for healthcare providers or pharmacists to record the dispensing date if required.

3.3 Storage

- **Room Temperature (up to 25°C / 77°F):** 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.
- **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.

3.4 Dosage

- **Standard Treatment Course:** The recommended regimen involves taking 1-2 capsules daily for a specified duration, typically around 60-180 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. Treatment is generally recommended to begin with one capsule.

3.5 Tapering

1. **Sequential Reduction:** After completing the therapeutic use of UltraBiome, a gradual phase-out protocol is recommended. The initial daily dose should be reduced step by step. During phase-out, it is advisable to skip the daily dose every third day at first (i.e., follow a 1-1-0 pattern). Next, administer the capsule only every third day (1-0-0). Dose adjustments should be made every 30 capsules. This approach ensures continuous reloading.
2. **Clinical Monitoring:** Patients should be closely monitored as the dose is reduced.
3. **Follow-Up:** Once treatment is complete—typically within 2–3 months after the final dose—it is recommended that the patient undergo follow-up to assess the therapy's outcomes and evaluate any changes in their condition.

4. Advantages

4.1 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.

4.2 High Efficacy

Clinical experience shows that using UltraBiome may help restore and maintain gut flora balance, supporting enhanced physical endurance and improved athletic performance—especially for those leading an active lifestyle. Its standardized microbiota graft effectively promotes microbial diversity, which is crucial not only for long-term intestinal health but also for overall physical well-being.

4.3 Ready-to-Use Therapy

UltraBiome is delivered as a fully prepared, rigorously tested product that can be directly administered by healthcare providers for home treatment. It eliminates the need for in-house stool processing, donor screening, or complex MTT preparation steps, ensuring standardized, high-quality therapy while saving time and resources.

4.4 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.

5. Pricing, Quantity Discounts, and Packaging Options

5.1 Pricing

The final price of UltraBiome may vary depending on distributor agreements and local regulations. For patients with obesity and/or type II diabetes, the average treatment period—following the initial buildup phase—is six months. After 60–90 days, based on a specialist's decision, an additional six-month cycle may follow. The therapy's phase-out can be planned according to the results achieved.

5.2 Quantity Discounts

Discounted rates may be available for bulk purchases, offering cost savings for larger orders.

5.3 Product Bundles

UltraBiome can be ordered in a minimum 30-capsule package, which corresponds to a one-month supply. Additional discounts based on packaging or volume may also be available, depending on the order size and distributor terms.

6. Additional Information

6.1 Donor Screening and Safety

- **Rigorous Screening:** Human microbiota of donors stool is meticulously screened according to applicable guidelines (e.g., EMA, WGO, EAGEN, or local health authority standards).
- **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 UltraBiome.

- **Elite Athletes Only:** The human microbiota used in UltraBiome capsules is exclusively sourced from donors with verified elite athletic status, demonstrating "ultra" performance capacity (e.g., a minimum of 10 km for swimming, 50 km for running, or 200 km for cycling). This level of performance is proven to correlate with outstanding physical and physiological indicators.

6.2 Drug Interactions

- **Antibiotics:** Concurrent antibiotic use may diminish the efficacy of UltraBiome. It is recommended to complete antibiotic treatment at least 48 hours before starting UltraBiome therapy.
- **Probiotics:** Data on interactions between UltraBiome and probiotic supplements is limited. Avoid concurrent probiotic use during UltraBiome treatment unless advised by a healthcare provider.

6.3 Known Side Effects

- **Common and Mild:** Gastrointestinal discomfort, bloating, flatulence, diarrhea, or constipation. These effects are usually temporary and resolve without medical intervention.
- **Rare but Serious:** Infections or allergic reactions may occur and require close monitoring. Any significant or unusual symptoms should prompt immediate medical evaluation and reporting.

6.4 Warnings and Precautions

- **Immunocompromised Patients:** Patients with severe immunodeficiency or those on immunosuppressive therapy require close monitoring 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 UltraBiome therapy.

7. Manufacturing Process and Quality Control

7.1 Donor Eligibility and Comprehensive Medical Evaluation

- **Thorough Pre-Donation Assessment:** All potential donors undergo a comprehensive medical evaluation before donation, including a detailed medical history, physical examination, and standard diagnostic tests. These ensure that any diseases or conditions transmissible via microbiota transfer are excluded to the best of current medical knowledge.
- **Dietary and Nutritional Requirements:** Donors adhere to a prescribed diet recommended by medical experts, including antibiotic-free animal proteins to support a stable, healthy microbiota. Regular medical evaluations are conducted to maintain the highest quality of donated material.

7.2 Serological Testing

- **Routine Screening:** Donors undergo at least two separate serological testing sessions 8 weeks apart to detect blood- and body-fluid-transmissible infections.
- **Tests Include:**
  - HIV 1–2 (Human Immunodeficiency Virus)
  - Hepatitis A, B, C, E
  - *Treponema pallidum* (syphilis)
  - Inflammatory markers in blood serum and stool
- **Eligibility:** Only donors with negative results across all repeated tests qualify for donation.

7.3 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 UltraBiome capsules.

7.4 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.

7.5 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.

7.6 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.

7.7 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.

7.8 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.

7.9 Ongoing Quality Oversight

- Quality Assurance (QA) teams routinely audit production processes, documentation, and QC test results to ensure compliance with GMP standards.
- Any deviations or out-of-specification (OOS) results are thoroughly investigated, and corrective actions are implemented to maintain product integrity and regulatory compliance.

8. Special Populations

8.1 Elderly Patients

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

8.2 Pediatric Use

- Currently, UltraBiome is not indicated for patients under 18 years of age. Research is ongoing regarding MTT safety and efficacy in pediatric populations.

9. Additional Considerations and Regulatory Status

9.1 Regulatory Classification

UltraBiome is classified as a Medical Laboratory Services (869015). Classification by EU regulatory authorities is anticipated by the end of 2026.

9.2 Prescribing and Dispensing

UltraBiome 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.

9.3 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.

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