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HospBiome

Service Overview

For healthcare professionals

Orally administered lyophilized human microbiota transplantation graft capsule for hospitalized patients with recurrent *Clostridioides difficile* infection

MicroBiome Bank

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This document is the official service overview of HospBiome, intended for healthcare professionals, institutional customers and distribution partners. It summarizes the composition, administration, quality assurance and regulatory status of the service. It is not a treatment protocol and does not replace the treating physician's individual judgement or patient counselling.

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Document details

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What is this document about? Chapters I–II describe the name and variations of the service, its indications, active substance and mechanism of action. Chapter III covers the method of use, packaging, storage conditions, dosage and tapering. Chapters IV–V summarize the advantages of the service together with the pricing, quantity discount and packaging framework. Chapter VI addresses donor screening, drug interactions, known side effects and precautions. Chapter VII details the manufacturing process and quality control steps, from donor eligibility to ongoing quality oversight. Chapters VIII–IX contain the considerations for special populations, the regulatory classification, the prescribing and dispensing conditions and the reporting obligations.

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Contents

I. Service Overview, General Information

I.1 Name of Service

HospBiome

I.2 Full Name of Service

HospBiome standardized intestinal microbiota graft for MTT

I.3 Service variations

HospBiome 5(L), HospBiome 5(XX), HospBiome 5(V) and HospBiome 15(V), where the Arabic number (5, 15) stands for the number of capsules within the container, while the Roman number (V, XX, L) indicates the dosage level, derived from the dry matter content of the lyophilized material.

- **HospBiome 5(L)** — L (50×) density, 5 capsules. Entry point at level 7. It may be opened as required and administered mixed in a neutral liquid, including via nasogastric tube. This is an option, not a requirement.
- **HospBiome 5(XX)** — XX (20×) density, 5 capsules. Entry point at level 6; the first dose reduction step of a therapy started at level 7.
- **HospBiome 5(V)** — V (5×) density, 5 capsules. Late hospital phase; transition to the home preparation.
- **HospBiome 15(V)** — V (5×) density, 15 capsules. The same capsule as the 5(V) — only the size of the pack differs. An economy pack size designed for Hungary.

Pack size ≠ therapy. The 5(V) and the 15(V) are clinically identical. Pack size is a matter of procurement quantity and cost, and therefore does not appear in the treatment matrix.

I.4 Description

HospBiome is an orally administered human microbiota transplantation (MT) service developed to restore healthy gut microbiota in patients experiencing recurrent *Clostridioides difficile* (*C. difficile*) infections (rCDI). Each capsule contains a standardized intestinal microbiota graft, optimized for scalable treatment protocols to ensure consistent therapeutic outcomes. Initially designed as part of the TransferBiome protocol, HospBiome is specifically formulated to enhance microbiota diversity and functionality. The procedure is carried out under stringent safety and efficacy standards, providing a dependable and effective solution for microbiota transfer therapy (MTT).

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

II.1 Indications

HospBiome is specifically designed for the treatment of *Clostridioides difficile* infections (CDI) in hospitalized patients. It is particularly recommended for individuals who have not responded adequately to antibiotic therapy or have experienced multiple recurrences of CDI. The service supports the restoration of gut health by introducing a highly diverse and well-balanced microbiota concentrate that helps suppress the overgrowth of pathogenic organisms.

II.2 Active Substance

HospBiome contains a biologically active substance obtained from carefully screened human donors, specifically designed for use in microbiome transfer therapy. Its main component is a standardized suspension of human colon-derived microbiota in a lyophilized form, prepared in accordance with strict quality and safety guidelines.

II.3 Mechanism of action

The active component in HospBiome is a diverse community of live gut microorganisms derived from healthy, screened donor stool. When ingested, these microorganisms colonize the patient's gastrointestinal tract, restoring microbial diversity and balance, which helps suppress the overgrowth of pathogenic bacteria like *C. difficile*.

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

III.1 Method of use

- Oral Administration: HospBiome 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 colonization conditions. Following this, other medications can be taken, and the regular daily routine may resume.
- Administration via Nasogastric Tube: if necessary, the capsules can be opened, and their contents emulsified in a neutral liquid (e.g., water, cold tea, plain yogurt) for administration. For patients with nasogastric feeding tubes, the emulsion can be directly administered through the tube, ensuring effective delivery of the treatment.
- 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: HospBiome 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 5 capsules; this is what we refer to as the packaging unit. The daily capsule count is given by the SIS band (level 6: starting 3/day, band maximum 5/day; level 7: 5/day), so the requirement depends on the classification and the length of the course; in institutional care the stock is matched to this.

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 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 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

The protocol fixes the dose in daily density units, from which the capsule count is derived. 1 density unit = 1 capsule of 1× density, that is, 1/1200 of the dry-matter content of the 150 g reference donation; daily density units = daily capsule count × density factor (V = 5×, XX = 20×, L = 50×). When changing preparation — in escalation and in dose reduction alike — the clinician calculates the density equivalent (density × capsule count) and raises or lowers within that. Viewed in capsule counts, the same step is sometimes a multiple increase and sometimes a reduction, which is why the capsule count in itself cannot be used as a basis for decision.

- Entry point at level 6 (SIS 70–79): HospBiome 5(XX), starting dose 3 capsules/day, band maximum 5 capsules/day (60 → 100 density units).
- Entry point at level 7 (SIS 80–100): HospBiome 5(L), 5 capsules/day, minimum 3 days (250 density units).
- Escalation: exclusively in the case of non-response, upwards, calculated in density equivalence. At level 6, 5(XX) 3 → 5/day, then 5(L) in the case of non-response. The LOT switch is an equivalent alternative here as well.
- Dose reduction: in response to the patient's improvement, downwards: 5(L) → 5(XX) → 5(V). Switch to 5(XX) if the stool frequency has demonstrably decreased and the patient can take fluids per os.
- Minimum course length: 10 days at the starting (or escalated) dose in every band. Below this, dose reduction is not recommended, regardless of how quickly the patient improves.
- Discharge: DiffBiome 30(V)+ at 4 capsules per day — the starting dose of level 5 — then dose reduction.
- 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

Reduction may only be initiated once **every** condition of the symptomatic gate is met:

Criterion	Requirement
Elapsed time	≥ 10 days at the starting dose
Bristol trend	Has moved persistently from the baseline 6–7 range towards 5–6, and then 4–5
Stool volume / count	The extreme daily stool count has substantially decreased compared with baseline
Blood in the stool	None

The trend of the Bristol scale and the stool count are to be read together: the improvement of the Bristol value in itself, without a decreasing stool count, is not sufficient.

- The course of dose reduction: −1 capsule every 3–4 days, as long as the gate holds.
- Relapse: if, according to the Bristol scale, the stool consistency returns to level 6–7, or the stool count rises, the dose must be returned to the band maximum, held there, and a LOT switch should be considered.

- Clinical Monitoring: patients should be closely observed during the tapering process for any signs of symptom recurrence or adverse reactions. If a relapse occurs, the maximum dosage can be reintroduced, and the treatment protocol may be repeated. After completing the repeat treatment, it is strongly recommended to switch to a different LOT.
- 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.

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 High Efficacy

Clinical evidence demonstrates that MTT capsules can significantly lower recurrence rates of *C. difficile* infections by effectively restoring microbial diversity and inhibiting the overgrowth of harmful pathogens.

IV.3 Ready-to-Use Therapy

HospBiome is delivered as a fully prepared, rigorously tested product that can be directly administered by healthcare providers. 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.

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 cost of HospBiome may vary depending on distributor agreements and local regulations. HospBiome is the preparation of levels 6 and 7; for these bands the scale prescribes institutional stock rather than a fixed capsule count. The actual quantity follows from the classification, the escalation and the course of dose reduction. Pricing is structured per one-day treatment unit, providing flexibility for healthcare providers to customize treatment plans.

V.2 Quantity Discounts

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

V.3 Product Bundles

HospBiome can be ordered in bundles containing a minimum of 120 treatment units, sufficient to treat 20 patients. Additional discounts based on packaging or volume may also be available, depending on the order size and distributor terms.

VI. Additional Information

VI.1 Donor Screening and Safety

Rigorous Screening: human microbiota of donors stool is comprehensively 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 HospBiome.

VI.2 Drug Interactions

Antibiotics: concurrent antibiotic use may diminish the efficacy of HospBiome. 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.

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.

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 HospBiome therapy.

VII. Manufacturing Process and Quality Control

VII.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.

VII.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.

VII.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 HospBiome capsules.

VII.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.

VII.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.

VII.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.

VII.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.

VII.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.

VII.9 Ongoing Quality Oversight

Quality Assurance (QA) personnel 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.

VIII. Special Populations

VIII.1 Elderly Patients

- Due to the potential for multiple comorbidities and concurrent medication use, HospBiome 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 HospBiome 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

HospBiome 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

HospBiome 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.