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PRODUCT DATA SHEET

FOR FINDBIOME MTT CAPSULES

1. Name of Product, General Information

1.1 Name of Product

FindBiome

1.2 Full Name of Product

FindBiome standardized intestinal microbiota graft for the purpose of determining donor–recipient compatibility.

1.3 Product variations

FindBiome is available in a 4×15 capsule format.

1.4 Description

FindBiome is an orally administered human microbiota compatibility test capsule specifically developed to facilitate the selection of compatible donor microbiota. Each capsule contains a standardized intestinal microbiota graft, optimized for setting up scalable treatment protocols and minimizing side effects. The purpose of the compatibility test conducted with FindBiome capsules is to ensure that the bacterial matrices of the donor and the recipient are aligned, thus laying the groundwork for a successful microbiota transfer therapy (MTT).

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

2.1 Indications

The purpose of the FindBiome package is to assist in selecting the most suitable batch (LOT) number formulation, i.e., the most compatible donor microbiota graft. As a result, TransferBiome therapy can be carried out with high efficiency, ensuring optimal microbial colonization for the recipient.

2.2 Active Substance

FindBiome is a standardized microbiota suspension derived from the human colon in freeze-dried form, enabling the performance of compatibility testing and the development of personalized therapy.

FindBiome capsules contain a carefully selected microbiota graft that temporarily colonizes the recipient's digestive tract and can be discontinued via a phase-out period, thus exerting a transient effect on the body. Production adheres to strict quality and safety standards, ensuring consistent efficacy and reliability of the product.

2.3 Mechanism of action

The active component of FindBiome is a diverse community of living gut microorganisms derived from the stool of healthy, screened donors. After ingestion, these microorganisms colonize the patient's gastrointestinal tract, restoring microbial diversity and balance, which helps curb the overgrowth of pathogenic bacteria—such as C. difficile.

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

3.1 Method of use

- **Oral Administration**: FindBiome 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: FindBiome capsules are packaged in dark glass bottles to ensure effective protection from light and maintain product quality. This packaging is designed to preserve the viability of the microorganisms and ensure consistent therapeutic efficacy throughout the treatment period.
- Each bottle contains 15 capsules, representing the 5 day dose referred to as the packaging unit.
- 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 product remains stable for up to 3 months (90 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 product is stable for up to 12 months.
- **Deep Freeze (below –20°C / –4°F):** Properly sealed and protected from light, the product can be stored for up to 5 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

- **Compatibility Test Protocol:** When using FindBiome, the objective is to select a compatible donor microbiota. The recommended dosage is 3 capsules per day for a specified period, which minimally involves a 32-day protocol.
- Recommended Dosing Schedule: The dosing schedule consists of four cycles (using four FindBiome packaging units), each comprising two phases: a testing phase (typically 5 days) and a phase-out phase (always 3 days). Consequently, the compatibility test lasts 4 × 8 days in total.
  - **Testing Phase (Days 1–5):** Take 3 capsules per day (15 capsules total).
  - **Phase-Out Phase (Days 6–8):** A 3-day break from taking capsules.
  - **Second Cycle (Days 9–13 and 14–16):** Use a new LOT-numbered product, followed by a phase-out period as described above, then proceed to the third and fourth cycles. This process can be repeated as needed until the most suitable batch (LOT) number product is identified.

- **Physician's Discretion:** The outcome of the compatibility test is assessed by the attending physician based on the patient's condition, tolerance, and logged data. During FindBiome use, keeping a food and symptom diary is essential for selecting the appropriate donor. Without proper documentation, the test results cannot be accurately evaluated, and the effectiveness of subsequent TransferBiome therapy cannot be guaranteed.

Taking FindBiome capsules follows the protocol determined by the physician and can be continued in a personalized manner to achieve the highest level of efficacy.

3.5 Tapering

1. **Sequential Reduction:** After taking one batch of FindBiome capsules, a minimum of three-day break is required to ensure that capsules from different donor batches (LOT numbers) do not overlap.
2. **Clinical Monitoring:** Patients' conditions should be closely monitored once they finish each capsule series.
3. **Follow-Up:** After treatment is completed (usually following the final dose), a consultation is recommended to document both objective and subjective symptoms. Based on these findings, the appropriate TransferBiome capsule batch (LOT) can be selected for therapeutic use.

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 evidence demonstrates that FindBiome capsules can reduce dysbiotic symptoms even during the compatibility test by contributing to the restoration of microbial diversity.

4.3 Ready-to-Use Therapy

FindBiome 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.

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 FindBiome may vary depending on distributor agreements and local regulations. For moderately severe conditions, the average treatment volume ranges between 30 and 60 capsules, whereas in severe cases that are resistant to antibiotic therapy, the treatment may require a larger quantity.

5.2 Quantity Discounts

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

5.3 Product Bundles

FindBiome is available in a package containing 4×15 capsules, which is sufficient to conduct a complete compatibility test. Certain packaging or volume discounts 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 the product.

6.2 Drug Interactions

- **Antibiotics:** Concurrent antibiotic use may diminish the efficacy of FindBiome. It is recommended to complete antibiotic treatment at least 48 hours before starting FindBiome therapy.
- **Probiotics:** Data on interactions between FindBiome and probiotic supplements is limited. Avoid concurrent probiotic use during FindBiome 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 FindBiome 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 FindBiome 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, FindBiome should be used with caution in elderly patients, accompanied by closer monitoring for any adverse effects or interactions.

8.2 Pediatric Use

- Currently, FindBiome 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

FindBiome is classified as a medical therapy (MTT) derived from substances of human origin. Classification by EU regulatory authorities is anticipated by the end of 2026.

9.2 Prescribing and Dispensing

FindBiome 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.

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