TECHNICAL SPECIFICATIONS

EXOSOMAS

GC
GENCELL
BIOTECHNOLOGY

Gencell EXOSOMES

EXOSOMES
Exosomes derived from mesenchymal stem cells.

PRODUCT NAME
Exosomes

QUALITATIVE AND QUANTITATIVE COMPOSITION
The solution contains:
Exosomes derived from mesenchymal stem cells, in different presentations:

7 Million Cells
14 Million Cells
21 Million Cells
28 Million Cells
42 Million Cells
49 Million Cells

PHARMACEUTICAL FORM AND USAGE CONSDERATIONS
Injectable solution.

PRESENTATION
The plastic container protects the single-serve vial, which contains 4 ml of the product.

THERAPEUTIC PROPERTIES

Mechanism of Action
Exosomes are microvesicles secreted by mesenchymal stem cells (MSC) that contain a variety of bioactive components, such as microRNAs, proteins, and mitochondria. After release, these vesicles are typically phagocytosed by various cell types, including immune system cells, facilitating their mechanism of action. Within phagocytic cells, the microRNAs released from exosomes integrate into nuclear DNA, where they regulate the transcription of specific genes involved in modulating the inflammatory response. This process results in a reduction in the expression of proinflammatory pathways and a decrease in autoimmune processes, promoting an anti-inflammatory environment and favoring the resolution of inflammation. Some of their specific bioactive characteristics are related to the content of microRNAs that regulate gene expression.

MSC contain several microRNAs such as miR-21, miR-146a, and miR-155. miR-21 and miR-146a play crucial roles, in regulating inflammation and the immune response, helping to reduce chronic inflammation and control autoimmune processes. miR-155 is involved in modulating inflammation and immunity, making it relevant for the treatment of inflammatory and autoimmune diseases.

Other relevant components are small proteins and growth factors. Among the proteins present in exosomes, TGF-β (Transforming Growth Factor Beta), IL-10 (Interleukin-10), and HGF (Liver Growth Factor) are notable. TGF-β and IL-10 are important in regulating the immune response and reducing inflammation, while HGF contributes to tissue regeneration and repair, being particularly useful in the recovery of damaged tissue. Within the clinical context, exosomes offer a broad range of therapeutic applications in chronic-degenerative diseases, autoimmune diseases, and chronic inflammation.

MSC-derived exosomes may offer significant benefits in the treatment of diseases such as osteoarthritis and osteoporosis; their ability to promote tissue regeneration and reduce chronic inflammation helps restore joint and bone function. Thanks to their immunomodulatory properties, MSC exosomes have the potential to treat autoimmune diseases by regulating immune responses and controlling autoimmunity. MSC exosomes have also been widely explored in dermatocosmetic treatments for their ability to repair and regenerate the skin. They can improve elasticity, reduce signs of aging, and promote a healthier and more youthful appearance.

Although this has not been their primary use, some international research groups have demonstrated their benefits in patients undergoing chemotherapy or treatments with folate antagonists such as methotrexate. MSC-derived exosomes can mitigate adverse effects, such as mucositis and neuropathy, and promote tissue regeneration, improving quality of life and treatment tolerance.

Placental MSC-derived exosomes have unique characteristics that distinguish them from other treatments Sources. The placenta, rich in stem cells with high regenerative and anti-inflammatory potential, provides a distinctive bioactive profile. These exosomes contain a specific composition of microRNAs and proteins, such as miR-21, miR-146a, miR-155, TGF-β, IL-10, and HGF, which enhance their therapeutic effects. This gives placental exosomes a greater ability to modulate immune responses and promote tissue repair compared to exosomes derived from other sources

CLINICAL DATA

a. Therapeutic Indications

Adjuvant in the treatment of various pathologies that can benefit from the regenerative and anti-inflammatory potential of MSC exosomes, such as chronic degenerative diseases, autoimmune diseases, and persistent inflammatory processes. It is also useful in patients receiving chemotherapy or treatments with folate antagonists such as methotrexate, helping to mitigate adverse effects and promoting tissue regeneration. It also has applications in dermato-cosmetic procedures and rejuvenation therapies, promoting skin repair and regeneration.

b. Dosage and Administration

Intravenous. Inject the patient with 100 milliliters of 0.9% saline solution and ensure proper placement of the IV. Next, retrieve the contents of the monovette and administer it slowly (not as a bolus) using the Y connector of the IV set. Inject the remaining saline solution over 15 minutes.

c. Contraindications

Sensitivity or allergies to any component of the formula.
Diagnosis of neoplasia.

d. Warnings and Precautions

There is no evidence for use in children under 12 years of age.
May contain traces of RPMI medium.

e. Interactions

To date, no extensive serious adverse interactions between MSC-derived exosomes and specific medications have been reported in the scientific literature.
However, given their immunomodulatory profile, caution is recommended when combining exosomes with therapies that affect the immune system.
Medications such as methotrexate, infliximab, and tocilizumab are known to affect the immune system.
Although there is no specific evidence on how MSC-derived exosomes interact with these medications, caution is advised. The combination could potentially intensify immunosuppression, which could increase the risk of infections or affect the efficacy of exosomes.
Careful monitoring and adjustment of concomitant therapies based on the patient's clinical response are essential. Consultation with a healthcare professional is recommended to assess any potential interactions and ensure safe and effective treatment management.

f. Pregnancy and Lactation

There are no research and study protocols under these conditions that support the safety of the product.

g. Adverse Effects

Dizziness, nausea, fainting, headache, vomiting, low-grade fever (temperature below 38°C), fatigue, or myalgia, which is self-limiting within 24 to 48 hours after application, may occur. Consult your doctor if any abnormal or previously undescribed symptoms appear.

ADDITIONAL DATA

a. Excipients

Saline solution 0.9%

b. Shelf Life

Once received, the product must be administered immediately or within 24 hours.

c. Storage and Preservation Conditions

Store away from direct sunlight and refrigerate between 2 and 8°C. Do not expose to sources of radiation or fire. Avoid freezing. Keep out of the reach of children and pets.

d. Waste Management

Dilute with 0.1% bleach and pour down the drain.
Freezing or refrigerating for longer than recommended reduces the product's viability, which may increase the risk of side effects.

Marketing Authorization Holder

Gencell ®

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