TECHNICAL SPECIFICATIONS

MESENCHYMAL STEM CELLS

By Gencell Biotechnology

INMUNOBOOST

GC
GENCELL
BIOTECHNOLOGY

Gencell® Células Natural Killer y Mesenchymal Stem Cells Mensenquimales

INMUNOBOOST

Autologous Natural Killer Cells and Mesenchymal Stem Cells.mesenquimales.

PRODUCT NAME

Inmunoboost

COMPOSITION

The solution contains:
Mesenchymal stem cells pre-treated with melatonin + allogeneic memory Natural Killer cells, a unique presentation composed of:

7 Million MSCs
7 Million allogeneic memory NK cells

PHARMACEUTICAL FORM AND USAGE CONSIDERATIONS

Iinjectable solution.

PRESENTATION

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

THERAPEUTIC PROPERTIES

Mechanism of Action

MSC possess key mechanisms for repairing injured tissues. Once administered, they adhere to the endothelium in affected tissues, facilitating their migration through diapedesis. At the site of injury, MSC exert immunomodulatory effects, reducing inflammation through the secretion of anti-inflammatory molecules such as IL-10 and TGF-β. They also inhibit apoptosis, stimulate cell proliferation, and promote the recruitment of regulatory T cells, aiding in tissue repair. Their ability to transdifferentiate into various cell types ensures regeneration in multiple damaged tissues. Furthermore, memory NK cells play a crucial role in the immune response against severe viral and bacterial infections.
These cells recognize and eliminate infected or neoplastic cells that have decreased MHC-I expression by releasing perforins and granzymes.

This process induces apoptosis in target cells. Memory NK cells also release cytokines such as IFN-γ, which activates macrophages and T lymphocytes, strengthening the host's adaptive immune response.

The combined use of MSC and memory NK cells optimizes regeneration and immune defense. While MSC promote tissue repair and improve endothelial function, NK cells attack intracellular pathogens. Furthermore, exosomes released by both cells mprove intercellular communication, accelerating the healing process. In immunosuppressive conditions, such as chronic infections or sepsis, this synergy allows for greater inflammatory regulation without triggering exaggerated immune responses.

This therapeutic approach is considered particularly effective in the treatment of immunosuppression, severe viral infections (such as CMV and EBV), bacterial infections, sepsis, and refractory autoimmune diseases, providing both immune support and efficient tissue regeneration without compromising inflammatory control.

CLINICAL DATA

a. Therapeutic Indications

Adjuvant in the treatment of immunosuppression, severe viral (e.g., CMV, EBV) and bacterial infections, chronic infections, sepsis, and autoimmune diseases refractory to treatment. This combination could be particularly useful in situations of immunosuppression where the immune system needs a boost without exacerbating inflammation.

b. Dosage and Administration

Intravenous. Inject the patient with 100 milliliters of 0.9% saline solution and ensure proper placement. Then, retrieve the contents of the monovette and administer it slowly (not as a bolus) using the IV set's Y connector. The remaining saline solution is administered 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 in children under 12 years of age.

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Administration should be carried out under strict medical supervision, especially during the first 24 to 48 hours after application. Immune-mediated adverse reactions, including serious or fatal events, have been reported and can occur in any organ system or tissue; reactions usually occur during treatment, but may manifest after discontinuation. May contain traces of RPMI medium.

e. Interactions

To date, no serious adverse interactions have been reported between MSC and specific medications.
However, due to their immunomodulatory profile, caution should be exercised when combining them with therapies that affect the immune system or coagulation.
Immunosuppressants such as methotrexate, infliximab, and tocilizumab may increase the risk of infections by potentiating immunosuppression, which could compromise MSC viability. Anticoagulants and antiplatelet agents may also increase the risk of bleeding during MSC administration.
Regarding memory NK cells, their cytotoxic activity may be altered by chemotherapeutic agents that affect their viability or function. Special caution should be exercised with antimetabolites such as methotrexate and 5-fluorouracil, which may compromise the ability of NK cells to proliferate and eliminate intracellular pathogens. Furthermore, topoisomerase inhibitors such as irinotecan and etoposide, and alkylating agents such as cyclophosphamide and ifosfamide, may reduce the effectiveness of NK cells by causing myelosuppression or cellular stress. Therefore, the administration of MSC and NK cells should be carefully planned to minimize potential interactions with other medications, especially those that compromise the immune response or increase the risk of adverse effects.

f. Pregnancy and Lactation

Evidence suggests that the use of this product is not recommended during pregnancy and breastfeeding. Due to the specific physiological conditions at these stages, use of the medication may pose a risk to the fetus and alter milk production or composition. An increase in NK cells could cause complications both in fetal development and during breastfeeding. If an alternative to this medication is not prescribed, the infant should be monitored for adverse effects and/or adequate milk intake

g. Adverse Effects

Vertigo, nausea, fainting, headache, vomiting, low-grade fever (temperature below 38°C), fatigue, or myalgia may occur, which is self-limiting within 24 to 48 hours after application.

Hypersensitivity reactions, although rare, may include hives or a rash. Systemic inflammatory syndrome, resulting from a transient increase in proinflammatory cytokines, can cause high fever, hypotension, and severe flu-like symptoms.

ADDITIONAL DATA

a. Excipients

Saline solution 0.9%

b. Shelf Life

After receiving the product, it 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 and shaking. Keep out of 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®