

TECHNICAL SPECIFICATIONS

GC
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BIOTECHNOLOGY



MUSE CELLS

Gencell® Growth Factors

MUSE CELLS®

Stress-resistant differentiated multi-lineage cells.

PRODUCT NAME

Muse Cells.

COMPOSITION

The solution contains:

Multilineage-differentiating stress-enduring (Muse) cells, available in various presentations:

10	Million cells
25	Million cells
50	Million cells

PHARMACEUTICAL FORM AND USAGE CONSIDERATIONS

Injectable solution.

PRESENTATION

The plastic container protects the monovette containing 4 mL of the product.

THERAPEUTIC PROPERTIES

Muse cells are a subpopulation of non-tumorigenic endogenous pluripotent cells, identified by SSEA-3⁺ expression. They are found in adipose tissue, umbilical cord, and placenta, representing a minimal fraction (0.01–0.03%) of mononuclear cells. Unlike mesenchymal stem cells (MSCs), Muse cells possess moderate pluripotency, stress resistance, selective homing to injured tissues, and an intrinsic immune privilege system that allows their allogeneic administration without immunosuppressants or HLA matching.

MECHANISM OF ACTION

Muse cells exert their therapeutic action through a set of regenerative, immunomodulatory, and anti-inflammatory mechanisms. After intravenous administration, they recognize damaged tissues through sphingosine-1-phosphate (S1P) released by damaged cells, selectively migrating to the site of injury. This allows them to selectively migrate to the site of injury and spontaneously differentiate into the cell types of the affected tissue, replacing necrotic or apoptotic cells without the need for external stimulation.

In parallel, they secrete a wide range of cytokines and trophic factors (IL-10, TGF- β , PGE₂, HGF, VEGF, G-CSF, MMPs) that reduce inflammation, inhibit fibrosis, promote angiogenesis, and stimulate tissue repair. In addition, Muse cells express HLA-G (\approx 90%) and lack HLA-DR, which suppresses T, B, and NK lymphocytes and macrophages. Together, these mechanisms give Muse cells a unique therapeutic profile, combining structural regeneration, inflammatory response control, and prolonged immunological stability.

CLINICAL DATA

Therapeutic Indications

Muse cells have shown efficacy as adjuvants in pathologies that benefit from regenerative potential such as acute myocardial infarction (reduction of infarct area and improved ventricular function), cardiac ischemic damage, ischemic stroke (neuronal regeneration and functional recovery), epidermolysis bullosa (dermal repair and collagen VII/XVII synthesis), amyotrophic lateral sclerosis (neuroprotection and reduced muscle atrophy), spinal cord injury (motor improvement) and chronic nephropathies (decreased fibrosis and parenchymal regeneration), acute respiratory distress syndrome due to COVID-19 and severe pancreatitis (reduction of proinflammatory cytokines and necrosis), and neonatal hypoxic-ischemic encephalopathy (neuroprotection and preservation of the blood-brain barrier).

Dosage and Administration

Intravenous. Inject the patient with 100 mL of 0.9% saline solution and verify proper placement. Retrieve the contents of the monovette and administer the suspension slowly and without a bolus through the IV set's Y connector. Complete the infusion by administering the remaining saline solution within 15 minutes.

Contraindications

- Hypersensitivity or allergy to any component of the formulation.
- Confirmed diagnosis of neoplasia.

Warnings and Precautions

- There is no evidence regarding safety or efficacy in children under 12 years of age.
- The product may contain traces of culture medium.

Interactions

To date, no serious adverse interactions between MUSE cells and specific medications have been documented in the scientific literature. However, due to their immunomodulatory profile, caution is advised when combining them with drugs that act on the immune or coagulation systems. Concomitant use of immunosuppressants such as methotrexate, infliximab, or tocilizumab may potentiate immunosuppression, thereby increasing the risk of infections and potentially affecting MUSE cell viability. Likewise, the use of anticoagulants or antiplatelet agents increases the risk of bleeding.sangrado

Pregnancy and Lactation

The use of MUSE therapies is contraindicated during pregnancy and breastfeeding, as there are no clinical studies supporting their safety during these periods. It is unknown whether the formulation components may affect fetal development or the health of the infant.

Adverse effects

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

Rare adverse reactions have been reported in the literature, including hypersensitivity (hives or rash), thromboembolism, chest pain, arrhythmias, dyspnea, and numbness at the injection site or in the extremities. Consult a physician if you experience any abnormal or unexplained symptoms.

REFERENCES

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4. Hori, E., Hayakawa, Y., Hayashi, T., Hori, S., Okamoto, S., Shibata, T., ... & Kuroda, S. (2016). Mobilization of pluripotent multilineage-differentiating stress-enduring cells in ischemic stroke. *Journal of Stroke and Cerebrovascular Diseases*, 25(6), 1473-1481.
5. Suzuki, T., Sato, Y., Kushida, Y., Tsuji, M., Wakao, S., Ueda, K., ... & Hayakawa, M. (2021). Intravenously delivered multilineage-differentiating stress enduring cells dampen excessive glutamate metabolism and microglial activation in experimental perinatal hypoxic ischemic encephalopathy. *Journal of Cerebral Blood Flow & Metabolism*, 41(7), 1707-1720.

ADDITIONAL DATA

a. List of Excipients

0.9% saline solution.

b. Shelf Life

After receipt, the product should be administered immediately or within a maximum of 24 hours.

c. Storage and preservation conditions

Store refrigerated between 2 and 8°C, away from direct sunlight. Do not expose to radiation sources or open flames. Avoid freezing. Keep out of reach of children and pets.

d. Waste Management

- Dilute with 0.1% bleach and dispose of down the drain.
- Refrigeration for longer than recommended decreases the product's viability and may increase the risk of side effects.

Marketing Authorization Holder.

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