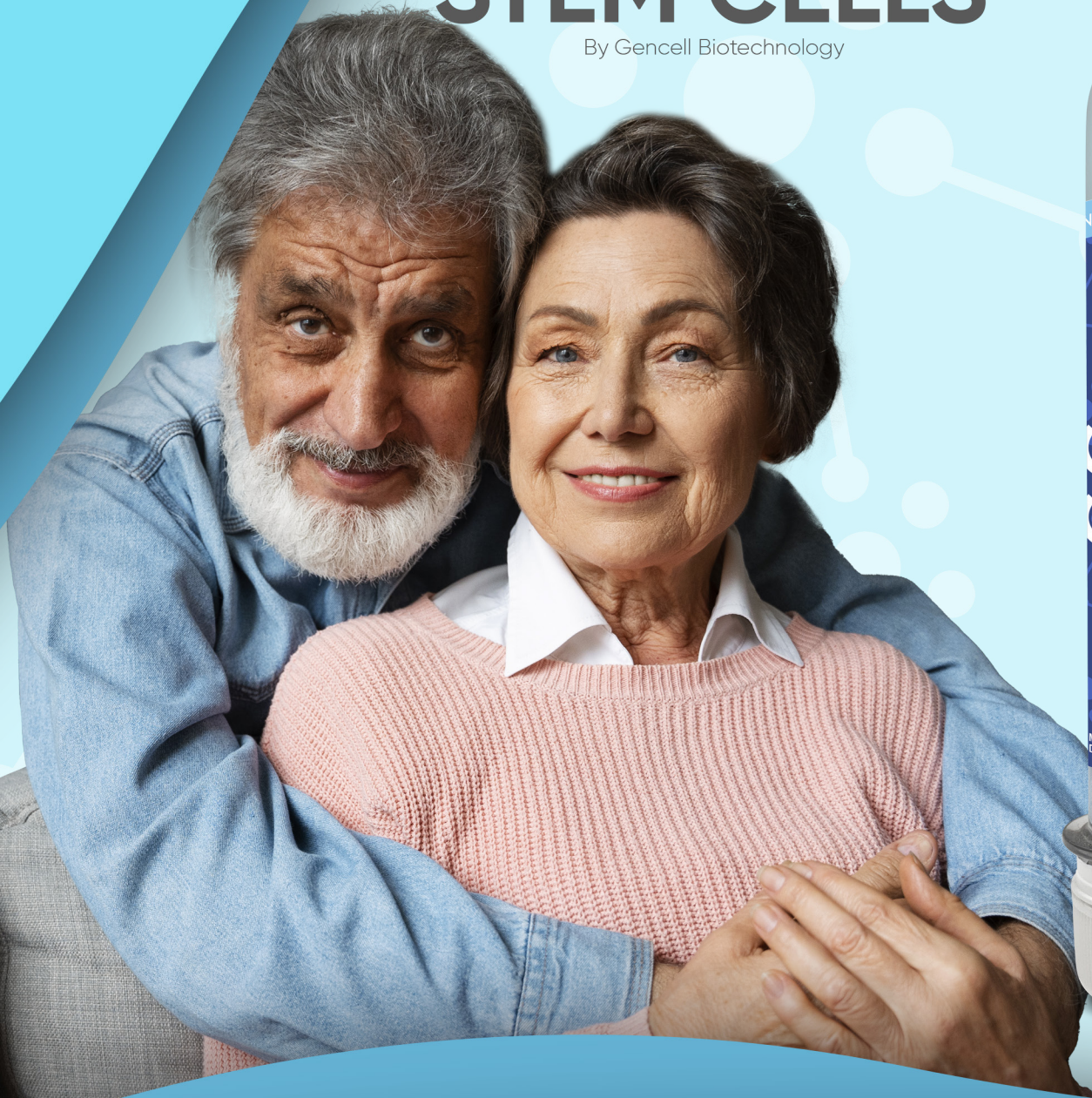


TECHNICAL SPECIFICATIONS

MESENCHYMAL STEM CELLS

By Gencell Biotechnology



NATIVAS

GC
GENCELL
BIOTECHNOLOGY

MESENCHYMAL STEM CELLS

By Gencell Biotechnology

Gencell® Mesenchymal Stem Cells

CTM NATIVE

Mesenchymal Stem Cells

PRODUCT NAME

CTM NATIVE

COMPOSITION

The solution contains:

Native 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 CONSIDERATIONS

Injectable solution.

PRESENTATION

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

THERAPEUTIC PROPERTIES

Mechanism of Action

Mesenchymal stem cells (MSCs) exhibit a wide range of mechanisms of action that significantly contribute to the repair and regeneration of injured tissues. Once administered intravenously, MSCs enter the bloodstream and, guided by injury signals such as cytokines and chemokines, selectively adhere to the endothelium of tissues where the expression of cell adhesion molecules has increased. This process facilitates their diapedesis—that is, their passage through the vascular wall—allowing them to efficiently migrate to the specific site of injury.

Once in the damaged area, MSCs initiate a complex and coordinated tissue repair process.

Among their main mechanisms, the following stand out:

1. Immunomodulation and inflammation reduction:

MSCs play a crucial role in modulating immune responses. Through the secretion of anti-inflammatory molecules and immune cell modulation, they help reduce chronic inflammation, creating a more favorable environment for tissue regeneration.

2. Secretion of bioactive molecules:

MSCs release a variety of growth factors, cytokines, and chemokines that not only reduce inflammation but also promote healing and regeneration. These include interleukins, growth factors, and proteins that enhance angiogenesis and tissue repair.

3. Proliferation and recruitment of regulatory T lymphocytes:

MSCs increase the proliferation and activation of regulatory T cells, which play a key role in suppressing uncontrolled immune responses particularly beneficial in autoimmune disorders and transplant rejection prevention.

4. Inhibition of apoptosis:

MSCs inhibit programmed cell death in damaged cells, helping to preserve surrounding tissues and prevent further deterioration of the injured area.

5. Stimulation of cell proliferation:

Through the secretion of growth factors, MSCs promote the proliferation of progenitor and other cell types essential for tissue repair and regeneration.

6. Transdifferentiation and directed differentiation:

MSCs have the ability to transdifferentiate into different cell types, adapting to the specific needs of the damaged tissue. This cellular plasticity allows them to become functional cells of the required type at the site of injury, such as osteocytes in bone or myocytes in cardiac muscle.

These combined mechanisms make mesenchymal stem cells a powerful and versatile therapeutic tool, with potential applications across a wide range of pathologies—from chronic degenerative diseases to autoimmune disorders and acute injuries.

Their ability to modulate inflammation, repair tissues, and promote cellular regeneration positions them as a promising therapeutic option in regenerative medicine.

CLINICAL DATA

a. Therapeutic Indications

Adjuvant in the treatment of various pathologies that may benefit from the regenerative potential of Mesenchymal Stem Cells, such as chronic degenerative diseases, autoimmune disorders, and chronic inflammatory processes.

They are the preferred option when no specific targeted cell effect is required, allowing their use in dermocosmetic and rejuvenation procedures.

b. Dosage and Administration

Intravenous route.

Cannulate the patient with 100 mL of 0.9% saline solution and ensure correct placement of the venous line. Retrieve the content of the monovette and administer it using the Y-connector of the venoclysis set slowly (not as a bolus). Infuse the remaining saline solution over approximately 15 minutes.

c. Contraindications

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

d. Warnings and Precautions

No evidence is available regarding safety in children under 12 years of age.
The product may contain traces of RPMI medium.

e. Interactions

To date, there are no extensive reports of severe adverse interactions between MSCs and specific medications in scientific literature. However, due to their immunomodulatory profile, caution is recommended when combined with therapies that affect the immune or coagulation systems. Immunosuppressants such as Methotrexate, Infliximab, and Tocilizumab may intensify immunosuppression, increasing the risk of infections or compromising immune response and MSC viability. Anticoagulants and antiplatelet agents may increase the risk of bleeding.

f. Pregnancy and Lactation

The use of Mesenchymal Stem Cell-based therapies is contraindicated during pregnancy and lactation, as there are no research protocols or studies supporting their safety under these conditions.

It is unknown whether any component of the formulation could cause harm during fetal development.

g. Adverse Effects

Possible side effects include dizziness, nausea, syncope, headache, vomiting, mild fever (temperature $<38^{\circ}\text{C}$), fatigue, or myalgia, which are self-limiting within 24–48 hours after application.

Rare adverse reactions reported in the literature include hypersensitivity (such as urticaria or rash), thromboembolism, chest pain, irregular heartbeat, shortness of breath, and numbness in the injection area or extremities.

Consult your physician if any abnormal or previously undescribed symptoms occur.

ADDITIONAL DATA

a. Excipients

0.9% saline solution

b. Shelf Life

After receipt, the product must be administered immediately or within no more than 24 hours.

c. Storage and Preservation Conditions

Store in a place protected from direct sunlight and refrigerated between 2 and 8 °C.

Do not expose to radiation or fire. Avoid freezing.
Keep out of reach of children and pets.

d. Waste Management

Dilute with 0.1% chlorine and dispose through the drain.
Freezing or refrigerating beyond the recommended period reduces product viability, which may increase the likelihood of side effects.

Marketing Authorization Holder

Gencell®