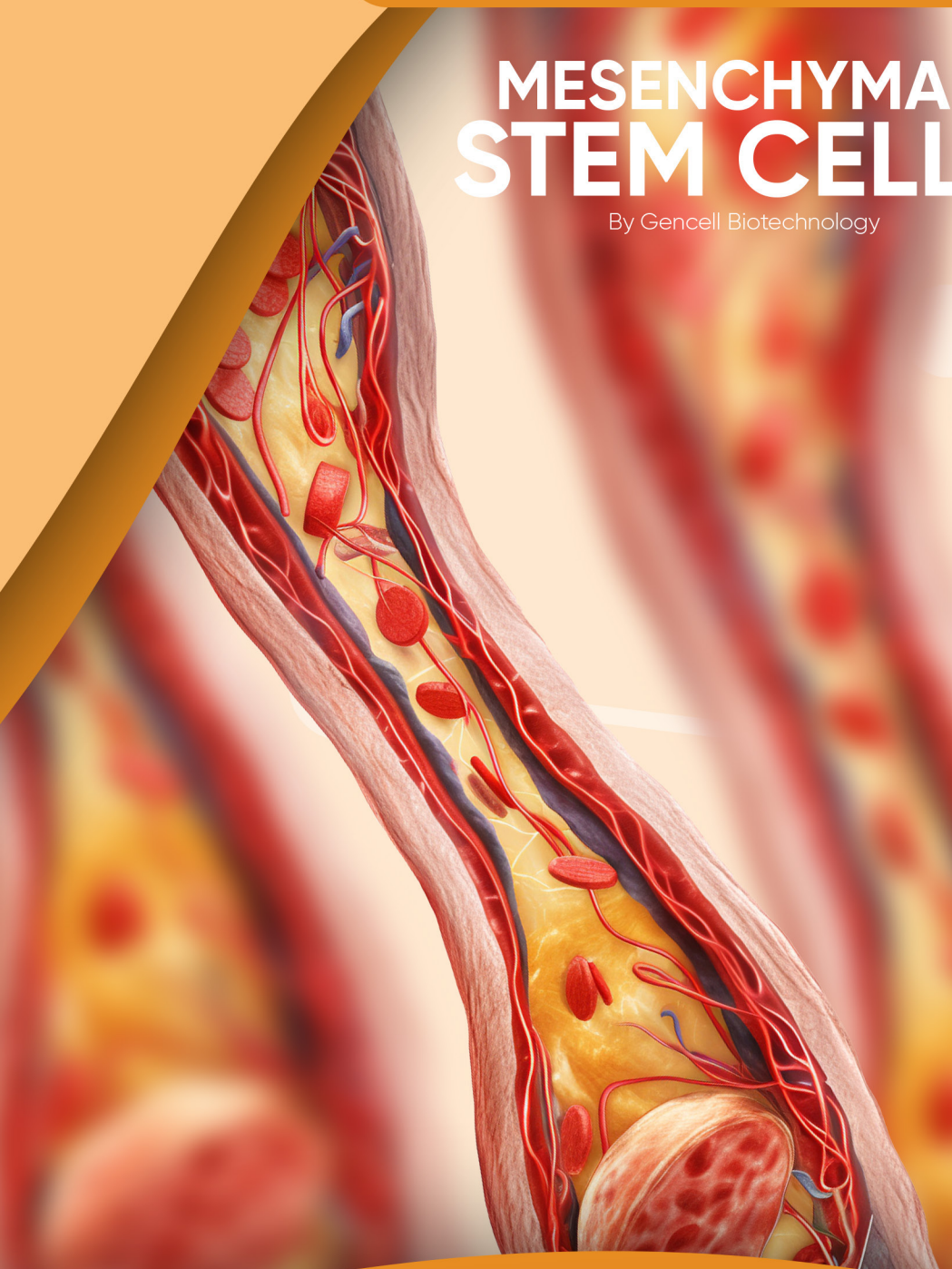
TECHNICAL SPECIFICATIONS

MESENCHYMAL STEM CELLS

By Gencell Biotechnology



METABÓLICA

GC GENCELL BIOTECHNOLOGY

MESENCHYMAL STEM CELLS

By Gencell Biotechnology

Gencell® Mensenchymal Stem Cells

CTM METABOLIC
Mensenchymal Stem Cells

PRODUCT NAME
CTM METABOLIC

COMPOSITION
The solution contains Mesenchymal Stem Cells in the following 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 the product.

THERAPEUTIC PROPERTIES

Mechanism of Action
Mesenchymal stem cells (MSCs) play a crucial role in the repair of damaged tissues through various mechanisms of action. Upon entering the bloodstream, MSCs adhere to the endothelium of injured tissues, where cell adhesion molecules are upregulated. This process facilitates their migration to the site of injury and the initiation of the repair process. The mechanisms by which MSCs contribute to tissue repair include:

Modulation of Inflammation:
MSCs secrete anti-inflammatory molecules that regulate the immune response and reduce inflammation at the injury site.

Stimulation of the Immune System: They promote the proliferation and recruitment of regulatory T lymphocytes, which are essential to prevent excessive immune responses.

Promotion of Cellular Regeneration: They stimulate cell proliferation in the damaged area, facilitating tissue regeneration.

Cellular Adaptation:
They undergo transdifferentiation to become the required cell type, achieving more specific and effective repair at the injury site.

Endothelial damage caused by elevated LDL cholesterol levels is a critical factor in the development of cardiovascular diseases. Metabolic mesenchymal stem cells (MSCs) are pretreated with evolocumab, a monoclonal antibody that binds to proprotein convertase subtilisin/kexin type 9 (PCSK9). PCSK9 is a molecule that promotes the ubiquitination and degradation of the low-density lipoprotein receptor (LDLr). By inhibiting PCSK9 activity, evolocumab maintains LDLr availability on the cell membrane, enabling greater LDL cholesterol uptake and promoting increased lipid turnover.

This combined approach may be beneficial in the treatment of familial hypercholesterolemia and mixed dyslipidemias. In familial hypercholesterolemia, the use of MSCs pretreated with evolocumab can enhance the cells' ability to regulate LDL cholesterol levels, thereby reducing harmful lipoproteins in the blood. In mixed dyslipidemias, this strategy not only helps decrease LDL cholesterol but may also optimize the overall lipid profile, improving lipid homeostasis and reducing the risk of cardiovascular diseases associated with lipid disorders.

The combination of MSCs with evolocumab offers a dual benefit: while evolocumab optimizes the lipid profile and reduces endothelial damage, MSCs can enhance the regeneration of damaged endothelial tissues and improve overall lipid homeostasis by reducing systemic inflammation related to lipid overload. Together, these effects contribute to better cardiovascular and metabolic health.

CLINICAL DATA

a. Therapeutic Indications

Indicated as an adjuvant in the treatment of familial hypercholesterolemia and mixed dyslipidemias.

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 through the Y-connector of the venoclysis set slowly (not as a bolus), followed by the infusion of the remaining saline solution over 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.
Use under strict medical supervision.

e. Interactions

To date, there are no extensive reports of serious adverse interactions between MSCs and specific medications in the scientific literature. However, due to their immunomodulatory profile, caution is recommended when combining them with therapies that affect the immune system or coagulation. Immunosuppressants such as Methotrexate, Infliximab, and Tocilizumab may intensify immunosuppression, increasing the risk of infections or compromising the immune response and the viability of MSCs. Anticoagulants and antiplatelet agents may increase the risk of bleeding.
Evolocumab, a PCSK9 inhibitor primarily used to reduce LDL cholesterol levels, has not shown significant drug interactions in the current literature. However, a few moderate interactions have been identified, such as with efgartigimod alfa and rozanolixizumab, both used in autoimmune and neuromuscular diseases. These medications could alter the immune response when used in combination with evolocumab. Although evolocumab has no known severe interactions, it is always advisable to monitor patients receiving multiple therapies that modify the immune system, due to the potential risk of unexpected effects.

g. Adverse Effects

Possible side effects include dizziness, nausea, headache, vomiting, mild fever (temperature <38°C), fatigue, or myalgia, which are self-limiting within 24–48 hours post-application.
Rare adverse reactions reported in the literature include hypersensitivity (such as urticaria), thromboembolism, chest pain, irregular heartbeat, shortness of breath, and numbness at the injection site 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®