

TECHNICAL SPECIFICATIONS



exocell

By Gencell Biotechnology

GC
GENCELL
BIOTECHNOLOGY

Gencell® Growth Factors

EXOCELL

Allogeneic Placenta-Derived Fibroblasts

PRODUCT NAME

EXOCELL.

COMPOSITION

The solution contains:

Allogeneic placenta-derived fibroblasts, available in the following concentrations:

- 3.5 Million Cells
- 7 Million Cells
- 14 Million Cells

PHARMACEUTICAL FORM AND USAGE CONSIDERATIONS

Injectable solution.

PRESENTATION

The plastic container protects the monovette, which contains 4 ml of the product.

THERAPEUTIC PROPERTIES

Mechanism of Action

With aging, the skin experiences a decline in its integrity, function, and regenerative capacity. However, allogeneic fibroblasts derived from perinatal tissues, such as those in EXOCELL, offer an innovative solution for skin repair. These cells have the ability to migrate specifically to sites of skin damage, where they release cytokines that activate regenerative processes, replacing damaged cells and restoring skin structure and function.

EXOCELL cells stand out for their low immunogenicity and remarkable adaptability to the environment in which they are applied. Once administered, they not only inhibit the activity of matrix metalloproteinases (MMPs), which are responsible for the degradation of the extracellular matrix, but also stimulate the proliferation of the patient's dermal fibroblasts. This process is essential for skin regeneration, as it promotes the production of collagen and other structural components.

Furthermore, the cytokines secreted by these cells, such as FGF, EGF, VEGF, NGF, PDGF, CSF, and TNF, play a crucial role in tissue repair. These molecules not only improve blood circulation and promote the formation of new vessels, but also support the regeneration of skin tissue, increasing skin thickness and promoting the production of extracellular matrix.



CLINICAL DATA

a. Therapeutic Indications

This product is indicated for facial rejuvenation procedures through subdermal application.

Placenta-derived allogeneic fibroblasts have demonstrated the ability to improve skin texture, reduce wrinkles, and enhance skin firmness and elasticity. These effects contribute to a more youthful and revitalized appearance, making it an effective option for patients seeking to counteract the signs of skin aging.

b. Dosage and Administration

Subdermal application.

The product is administered via injection using a 27–31G needle with a length of 5–6 mm, in the targeted areas of the face. Administration is recommended by a healthcare professional trained in aesthetic medicine procedures, with an interval of 4 to 6 weeks between sessions.

c. Contraindications

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

d. Warnings and Precautions

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

e. Interactions

To date, there are no extensive reports of serious adverse interactions between allogeneic fibroblasts and specific medications in the scientific literature. However, caution is recommended when combining them with therapies that affect the immune system. Immunosuppressants such as methotrexate, infliximab, and tocilizumab can intensify immunosuppression, increasing the risk of infections or compromising the immune response and viability of allogeneic fibroblasts.

f. Pregnancy and Lactation

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

g. Adverse Effects

Edema, erythema, local pain, and low-grade fever (temperature less than 38°C) may occur, which is self-limiting within 24 to 48 hours after application.

Some rare reactions that have been reported in the literature include hypersensitivity reactions (urticaria or rash).

ADDITIONAL DATA

a. List of 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 refrigerate between 2°C and 8°C. Do not expose to sources of radiation or fire. Avoid freezing. Keep out of reach of children and domestic animals.

d. Waste Management

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

Marketing Authorization Holder

Gencell®