TECHNICAL SPECIFICATIONS

# MESENCHYMAL STEM CELLS

By Gencell Biotechnology


# BIODENT ÓSEO

GC
GENCELL
BIOTECHNOLOGY

## Gencell Mesenchymal stem cells

**BIODENT osseous**
Mesenchymal stem cells.

**PRODUCT NAME**
BIODENT osseous

**COMPOSITION**
The solution contains: Placental-derived mesenchymal stem cells, in a presentation of:

5 million cells

**PHARMACEUTICAL FORM AND USAGE CONSIDERATIONS**
Sterile injectable solution.

**PRESENTATION**
The plastic container protects the single-dose vial, which contains 1 ml of the product.

## THERAPEUTIC PROPERTIES

**Mechanism of Action**
Biodent Osseo is an innovative product that combines the properties of mesenchymal stem cells with demineralized bone matrix to enhance bone regeneration in the oral region. Mesenchymal stem cells are known for their ability to secrete trophic factors that promote bone tissue repair through antiapoptotic, antifibrotic, angiogenic, and mitotic effects. These factors not only promote alveolar bone regeneration but also improve dental implant integration. Furthermore, Biodent Osseo leverages extracellular vesicles, such as exosomes and microvesicles, secreted by mesenchymal stem cells, which act as key regulators in tissue repair and immune modulation. These vesicles help reduce local inflammation and promote an environment conducive to bone regeneration, inhibiting the proliferation of immune cells that could interfere with the integration process. The use of Biodent Bone has been shown to increase the levels of osteogenic markers such as osteopontin and osteocalcin, underscoring its effectiveness in promoting bone regeneration of bone formation and consolidation in areas compromised by bone defects or loss. This makes Biodent Bone an ideal therapeutic option for patients who require effective bone regeneration before or during dental implant placement.

## CLINICAL DATA

**a. Therapeutic Indications**
Biodent Osseo is indicated for bone reconstruction and regeneration in patients who require dental implant placement or have suffered bone loss due to periodontal disease, trauma, or surgery. Mesenchymal stem cells, when combined with demineralized bone matrix, offer an advanced therapeutic option to improve implant integration and restore lost bone structure, promoting both function and aesthetics in the oral region

**b. Dosage and Administration**
Administration route and dose: as prescribed by the physician. Biodent Bone is applied by mixing mesenchymal stem cells with demineralized bone matrix directly at the site of the bone defect or in the surgical site prepared for dental implant placement. Due to the viscosity of the mixture, a spatula is recommended. The mixture is placed on the area of application. It should be distributed evenly over the affected area to ensure optimal bone tissue regeneration. It is recommended that it be administered by a healthcare professional trained in oral and maxillofacial surgery.

**c. Contraindications**
Sensitivity 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 CTM and specific medications in the scientific literature. However, given 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 CTM 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 breastfeeding, as there are no research protocols or studies supporting their safety in these conditions.

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

### g. Adverse Effects

Edema, erythema, and local pain may occur, which is self-limiting within 24-48 hours after application. Rare adverse reactions reported in the literature include hypersensitivity, such as hives, thromboembolism, chest pain, irregular heart rhythm, difficulty breathing, and numbness in the puncture area or extremities. Consult your doctor if you experience any abnormal or previously unexplained symptoms.

## ADDITIONAL DATA

### a. Excipients

0.9% saline solution

### b. Shelf Life

After receipt, the product must be administered immediately in 24 hours.

### c. Storage and Preservation Conditions

Keep protected from direct sunlight and refrigerated between 2 and 8°C.
Do not expose to sources of radiation or fire. Avoid freezing. Keep out of the reach of children and pets.

### d. Waste Management

Dilute with 0.1% chlorine bleach and dispose of down the drain.
Freezing or refrigeration for longer than recommended reduces the viability of the product, which may increase the risk of side effects.

### Marketing Authorization Holder

Gencell®