Barcelona Tissue Bank
BANC DE SANG I TEIXITS

AMNIOTIC MEMBRANE EXTRACT

63

BT7018

Specifications

The membrane extract is a freeze-dried product obtained from amniotic membrane. Each vial is reconstituted in 4 mL of sterilised water and contains the amount of extract required for 15 days treatment. The minimum duration of treatment is 30 days.

Clinical applications

- Ophthalmic use in patients with epithelial defects of the cornea
- Cases of dry eye secondary to autoimmune syndrome
- Corneal ulcers
- Adjuvant in cornea transplant surgery, and pterygium and symblepharon excision

For more information:
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Salut/ BANC DE SANG I TEIXITS

Tissue acquisition

The tissue comes from donors with controlled pregnancy. The standard serological screening includes: HIV-1/2 antibodies, HIV-antigen, HIV 1 -RNA, HBsAg, HBc antibodies, HBV-DNA, HCV-antibodies, HCV-RNA, syphilis and HTLV I/II antibodies.
Once the placenta is obtained, it is preserved until processing and preservation in the Tissue Bank.

Processing

All processes carried out at the Barcelona Tissue Bank (BTB) are subject to a quality system designed to meet the requirements established in the Good Tissue Practices (GTPs) principles and guides and the European Union's Good Manufacturing Practices (GMP). They also meet the requirements arising from the authorisations for investigational drugs, the requirements established in Royal Decree-law 9/2014 for the processing, preservation and distribution of tissues and cells for transplantation, the quality management requirements established in Standard ISO 9001 and the technical specifications for the products obtained, ensuring quality, safety and efficacy.

Processing consists of separating the amniotic membrane from the chorion and corresponding antibiotic decontamination (penicillin, streptomycin and amphotericin B). Next, the tissue is ground and centrifuged to obtain the extract. The process concludes with freeze-drying. After the final quality control, the tissue is made available for distribution and prescribed use in patients.

Storage

The membrane extract is stored at room temperature until used. The product expiry date is five years from its processing, as long as the integrity of the packaging is maintained. The tissue should not be used if any of the packaging is compromised.

Transport

The extract is packaged together with all the material necessary for its rehydration. It is transported at room temperature, placing the packaged product in a container, protecting its integrity at all times. The product expiry date is stated on the label and the attached documentation.

Coding

In compliance with the legal requirements of the Commission Directive (EU) 2015/565, all tissues are identified and labelled with the "Single European Code" (SEC). This code is a unique identifier that facilitates traceability and provides information on the main characteristics and properties of those tissues and cells distributed in the European Union. The SEC consists in 40 alphanumeric characters, representing the donation identification sequence and product identification sequence. The last 8 characters correspond to the expiry date of the product, represented in the format YYYYMMDD.

Traceability

The clinical use of tissues and cells of human origin provides major benefits for recipients. Like any product of human origin, their use is not free of risks, which although infrequent, can be serious.
A robust system is required, capable of placing, locating and identifying the cells and tissues at any point in the process, from donation to recipient, to ensure rapid intervention. This prevents damage or potential risk when the quality and safety of the donated tissues and cells are compromised. Each tissue is identified with a unique code to permit tracking from origin to destination.
Once the tissue is transplanted, the code must be attached to the recipient's clinical history. The tissue bank must be informed when it has been transplanted, providing the recipient's clinical history number or initials. The bank should also be informed if the tissue is not transplanted.

Biovigilance

If there is suspicion or evidence of a severe adverse reaction or effect in the recipient possibly related to the safety and quality of the transplanted tissue or cells, the physician must immediately contact the tissue bank or competent health authority.
A severe adverse reaction or adverse effect notification form is provided for each tissue.

Regulatory legislation on tissues

The Barcelona Tissue Bank has administrative authorisation no. E08796463 issued by the competent authority. The regulated activities include donation, acquisition, assessment, processing, preservation, storage and distribution. Human tissues processed under the control of the bank meet the requirements of Spanish legislation (Royal Decree law 09/2014) and European Directive 2004/23 and directives 2006/17/EC, 2006/86/EC, 2012/39/EU developing it.
BTB follows the standards of the principal scientific associations: *Asociación Española de Bancos de Tejidos* (AEBT), European Association of Tissue Banks (EATB), American Association of Tissue Banks (AATB), European Eye Bank Association (EEBA), and the recommendations of: Good Tissue Practices (Euro-GTP) and the Council of Europe EDQM Guide to the quality and safety of tissues and cells for human application.