Omnigen®

Instructions For Use

Please read before use

Product Description:
Omnigen is a Tereo® processed dehydrated human amniotic membrane, aseptically processed according to the regulatory standards of the Human Tissue Authority (HTA) Guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment.

Omnigen is a human tissue-based transplant allograft that contains non-living cells. Omnigen units may have an opaque appearance when dry which disappears upon rehydration.

Donor Selection:
Tissue is procured from eligible donors undergoing elective caesarean section, following voluntary informed consent. All donors are screened against approved donor selection criteria and comply with Annex A of the HTA Guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment.

Donor/Tissue Screening:
Donors are screened for risk factors, and clinical evidence of infection due to communicable diseases, along with other exclusionary criteria, through the review of the donor's medical records and medical/behaviour questionnaire.

A donor blood specimen is screened for infectious diseases in accordance with Annex B of HTA Guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment. These include the infectious diseases markers for:

HIV: Anti HIV1, HIV2 & p24	HIV-1 RNA Viral Load
Hepatitis B: HBsAg & anti-HBc	Hepatitis B Virus DNA
Hepatitis C: Anti-HCV-Ab	Hepatitis C Virus RNA
Syphilis: IgG/IgM & RPR	Hepatitis E Virus RNA
HTLV-I/II Antibody	Cytomegalovirus

Processing:
Omnigen is processed in a controlled environment using aseptic techniques to prevent contamination of the tissues.

Tissue decontamination is performed using an antibiotic-antimycotic solution containing Gentamicin, Imipenem, Polymyxin B Sulphate, Vancomycin and Nystatin prior to drying. **TRACES OF ANTIBIOTICS WILL BE PRESENT IN THE ALLOGRAFT.**

All Omnigen units are imaged, and quality assessed to eliminate defects before release.

Omnigen is primary packaged in a double barrier system. This allograft has not been terminally sterilised. All product batches undergo microbiological testing prior to release.

Storage Recommendations:
Omnigen is a dry preserved and stable product and should be stored between 2 °C – 25 °C until the stated expiry date. Keep away from extreme heat or direct sunlight.

In the UK, Omnigen is regulated by the HTA. Therefore, where the delivery address is in the UK the customer shall not hold any Omnigen for longer than 48 hours unless it holds a tissue storage licence to do so and shall make the local designated individual aware of such storage.

It is the responsibility of the international customers to follow international and national/local laws regarding the handling and storage of such products.

Application of Omnigen:
Omnigen is commonly used as a permanent inlay-graft (graft) or a temporary onlay-graft (patch) in ophthalmology to support body's natural healing process, and to provide a physical barrier to protect the wound.

Recommended Instructions for Use:
NOTE These recommendations are designed only to serve as general guidelines. They are not intended to supersede any institutional protocols or professional clinical judgement concerning patient care. Transplantation should be according to the clinical decision.

End users are advised that the outside of the outer pouch is not sterile and should not be placed within the sterile field during clinical application. Open the outer pouch to present the inner sterile pouch to the sterile surgical field or clean in-clinic environment. Open the sterile inner pouch to retrieve Omnigen. Omnigen is ready for use, but may be cut with scissors or trephine, and can be applied immediately without prior rehydration. Omnigen should be rehydrated for two minutes *in situ.*

Guidance to the orientation of the membrane can be found at:

Traceability:
It is a regulatory requirement for the supply and use of human tissue that the end user operates a system that allows full traceability of the use of human tissue products from donor to recipient and vice versa. A 40-digit Unique Identification Code (UIC/SEC) barcode labels are provided with the packaging and should be used as part of the traceability

system. All human tissue products must be recorded in a tissue logbook facilitate traceability to the recipient.

To record, track and assess your outcomes of your Omnigen transplantations, please visit the registry of amniotic membrane outcomes in ophthalmology (ROMEO Ophthalmology) through the following link: romeo.e-dendrite.com or scan the below QR code.

Incident Reporting:

If it is suspected that any adverse clinical outcomes are attributable to the use of Omnigen, please inform NuVision Biotherapies at: incident@nu-vision.co.uk or by telephone +44(0)115 784 0120 without delay. NuVision will provide the end user with an Incident Report Form if needed but which can be downloaded using the QR code below or from the NuVision webpage.

Patients should be informed to contact their doctor or nurse if they experience any side effects.

Regulatory Classification:

NuVision Biotherapies Limited is licensed by the Human Tissue Authority (HTA), (Licence No. 22656) to procure, test, process, store, distribute and export human tissue for clinical application.

For enquiries and further information, please contact NuVision Biotherapies:

NuVision Biotherapies Limited
MediCity, D6 Building
Thane Road
Nottingham
United Kingdom
NG90 6BH

info@nu-vision.co.uk
0115 784 0120
www.nu-vision.co.uk

Precautions:

- Confirm that the product supplied matches the product and size requested.
- Do not use Omnigen if the packaging is damaged or compromised. Contact NuVision immediately if any irregularities are observed e.g., labelling, shipping, or missing information, quoting the 40-digit Unique Identification Code (UIC/SEC).
- The content of one pack is intended for use in one patient only. Any remaining tissue is to be discarded (disposal in accordance with local regulations).
- Once opened, Omnigen must be used immediately.
- Omnigen must only be used by trained health professionals.

Warnings:

- Do not use on patients with a history of drug reactions to Gentamicin, Imipenem, Polymyxin B Sulphate, Vancomycin or Nystatin.
- As with the use of any human tissue, the possibility of infectious agent transmission cannot be eliminated completely, although all transmissible disease screening and microbial test results for this donor were satisfactory for human application. Any transplantation should be based on a clinical assessment of the risk versus the benefit of the patient.
- This also applies to unknown or emerging viruses, prions, and other pathogens. At present, there is no effective testing for variant Creutzfeldt-Jakob Disease (vCJD), nor any means of treatment. Although the residual risk of vCJD transmission is considered low, a residual risk may exist, and this should be considered.
- Patients should be consented for any procedure involving any human tissue, including Omnigen.
- Do not use if the product expiry date has lapsed, last 8 digits of the UIC/SEC in format YYYYMMDD.
- Excess unused material should be disposed of as clinical waste according to the local policy.

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