Sources & Production

Omnigen®

Distributed through

NEXT BIOLOGICS

Donor Selection

Omnigen is prepared only from amniotic membrane that has been selected and accepted from consenting pregnant UK donors who have met NuVision donor selection criteria. These criteria are based upon an analysis of risks related to the application of amniotic membrane allografts and comply with the European requirements of Annex I 'Commission Directive 2006/17/EC· Selection criteria for donors of tissues and/or cells (except donors of reproductive cells)'.

Donor Testing

All tissue donations are screened for infectious diseases in accordance with Annex II of 'Commission Directive 2006/17/EC· Laboratory tests required for donors (except donors of reproductive cells) as referred to in article 4(1)'. The mandatory and additional tests (*) applied are summarised in the table to below

Blood Test	Acceptable Result
HIV: Anti HIV1, HIV2	Negative / Non-reactive
Hepatitis B: HBsAg	Negative / Non-reactive
Hepatitis B: Anti HBc	Negative / Non-reactive
Hepatitis C: Anti-HCV-Ab	Negative / Non-reactive
Syphilis	Negative / Non-reactive
HTLV-Ab	Negative / Non-reactive
Cytomegalovirus*	Negative / Non-reactive
NAT HIV screen	Negative / Non-reactive
NAT HBV screen	Negative / Non-reactive
NAT HCV screen	Negative / Non-reactive

Donor Testing

Omnigen® is a Tereo® processed piece of dry preserved amniotic membrane donated by a consenting donor undergoing an elective caesarean section. The membrane has been processed in the UK by NuVision® Biotherapies Limited. It does not contain living cells. Omnigen is aseptically processed in a sterile environment and washed in an antibiotic cocktail containing· Gentamicin, Imipenem, Nystatin, Polymyxin B, Vancomycin. Traces of antibiotics may be present in Omnigen. This membrane has not been terminally sterilised.
It can be stored at room temperature up to 25°C until the stated expiry date. It is recommended not to store the product where it may be subject to extreme heat e.g. in sunlight. It should not be frozen.