

GM508 Cult-Active

Material included in the packing:

- 1 ml GM508 Cult-Active

Material not included in the packing:

- CO₂-incubator
- Petri-dishes
- LAF-bench (ISO5 environment)
- Microscope
- Test-tubes

Product code:

- 4 GM 508CULT-active1

Composition:

- NaCl, KCl, KH₂PO₄, MgSO₄·7H₂O, NaHCO₃, CaCl₂·2H₂O, Dextrose-Anhydrous, Na-Lactate, Na-Pyruvate, EDTA, Na-Alanyl-Glutamine, water, non-essential and essential amino acids, 1 % HSA, Gentamicin, Ca²⁺-ionophore A23187.

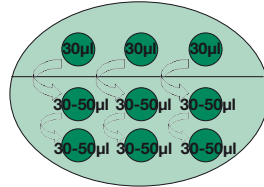
Intended use/Intended users

- GM508 Cult-Active is a ready-to-use bicarbonate-buffered medium designed to activate oocytes of patients with failed fertilization after previous Intracytoplasmatic Sperm Injection cycles. GM508 Cult-Active significantly increases fertilization rates in patients with complete fertilization failure or low fertilization rate (33%) after ICSI as well as for patients with severe male factor infertility.
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Instructions for use:

- GM508 Cult-Active must be equilibrated 4 hours in a tube not firmly closed at 5-7 % CO₂ and 37°C prior to use. Gynemed recommends a pH-value of 7.00 - 7.60. The corresponding CO₂-concentration should be checked out individually for every incubator.

- Prepare a microdrop-dish in the following way:



GM508 Cult-Active
30 µl/15 min

GM5051 Cult Media

- Right after the ICSI procedure incubate the oocytes for 15 minutes in the Ca²⁺-ionophore GM508 Cult-Active drops.
- Remove the oocytes from the GM508 Cult-Active and wash them in your culture media twice. This has to be done in a HEPES- or MOPS-free media, so i.e. GM501 Basic.
- Put the oocytes in your culture media for further culture.

Product specifications and quality control:

- GM508 Cult-Active is manufactured according to ISO 9001 and ISO 13485 standards.
- All raw materials are of highest available purity (European Pharmacopoeia and/or USP standard) if applicable.
- A certificate of analysis is available for each batch upon request from our website with respective lot number.
- GM508 Cult-Active is manufactured and tested according to the following specifications:

	Consult instructions of use		Do not use if package is damaged
	Temperature limitation		Sterilized using aseptic processing techniques (filtration)
	Lot number		Keep away from sunlight
	Use by		

pH (at 37°C, 6 % CO ₂)	7.00 - 7.60
Osmolality (mOsm/kg)	420 - 490
Sterility	steril - SAL 10 ⁻³ (Sterility Assurance Level)
Endotoxins (EU/ml)	< 0.25
MEA (Blastocysts after 96h in %) after 30 min of exposure (zygote stage)	≥ 80

Precautions and warnings:

- GM508 Cult-Active contains the antibiotic: Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
- The media contains human albumin solution (HAS), which is produced from blood of donors of certified US blood banks according to the guidelines of FDA. Source materials from which this product was delivered was found negative when tested for antibodies to HIV, Hbc, HCV and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test method can offer assurance that products delivered from human blood will not transmit infectious agents. Therefore, handle all specimens as if capable of transmitting HIV or hepatitis.
- Always wear protective clothing when handling specimens.
- Always work under strict hygienic conditions (ISO5 environment) to avoid possible contamination.
- Do not use the product if bottle, seal of the container or package is opened or defect when the product is delivered.
- Do not use the product if it becomes cloudy or shows any evidence of microbial contamination.
- Only for the intended use.

Storage instructions and stability:

- Shelf life is 6 months from time of manufacture.
- Store between 2-8°C.
- Do not freeze before use.
- Keep away from (sun) light.
- After opening the container do not use the product longer than 7 days.
- Do not use after expiration date.

For technical support:

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