GM501 Hyaluronidase

EN

GYNEMED

Material included in the package:
- 1 x 10 ml GM501 Hyaluronidase
- 5 x 1 ml GM501 Hyaluronidase

Material not included in the package:
- Incubator (at 37°C, no CO_2)
- Petri dishes
- Pipette suitable for denudation of oocytes
- LAF-bench (ISO5 environment)
- Mineral Oil
  (e.g. GM501 Mineral Oil)
- Washing medium
  (e.g. GM501 Wash)

Product code:
- 4 HY 0010 *(1 x 10 ml)*
- 4 HY 0001-5 *(5 x 1 ml)*

Composition:
- 80 IU/ml pharmaceutical grade hyaluronidase from bovine origin solved in HEPES-buffered medium, containing 4.00 g/liter human serum albumin.

Intended use/Intended users:
- GM501 Hyaluronidase is a ready-to-use solution designed to facilitate the mechanical removal of cumulus cells. Hyaluronidase digests the extracellular matrix in the cumulus-oocyte complex consisting of hyaluronic acid.
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Instructions for use:
- GM501 Hyaluronidase contains HEPES; no CO_2 incubation is required, just warm it up to 37°C (incubation in a CO_2 incubator will lower the pH below 7).
- Depending on the dishes, 100 µl (micodrops) or 400-600 µl (center-/4-well) of GM501 Hyaluronidase should be used for denudation.
- Additionally prepare 3-5 drops (100 µl) of washing medium (e.g. GM501 Wash) for oocyte washing.
- The dishes should be covered with Mineral Oil (e.g. GM501 Mineral Oil).
- Place the oocyte in the Hyaluronidase (up to max. 5 oocytes) for about 30 seconds.
- Using a fine pipette, transfer the partially denuded oocytes to the first washing drop.
- Remove the corona by repeatedly pipetting the oocytes.
- Use the other drops to further wash the denuded oocyte.

Product specifications and quality control:
- 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.
- The MSDS for GM501 Hyaluronidase is available upon request and can also be downloaded from our website.
- GM501 Hyaluronidase is manufactured and tested according to the following specifications:

pH (at 37°C)	7.30-7.60
Osmolality (mOsm/kg)	270-290
Sterility	sterile - SAL 10^{-3} (Sterility Assurance Level)
Endotoxins (EU/ml)	< 1.00
MEA (1-cell assay, blastocysts after 96h in %)	≥ 80

Precautions and warnings:
- Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot totally be excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albumin, manufactured to European Pharmacopoeia specifications by established processes.
- Handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens.
- Product does not contain any antibiotics. Always work under strict hygienic conditions (e.g. LAF-bench, ISO Class 5) to avoid possible contamination.
- Only for the intended use.

Pre-use checks:
- 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 discoloured, cloudy or shows any evidence of microbial contamination.

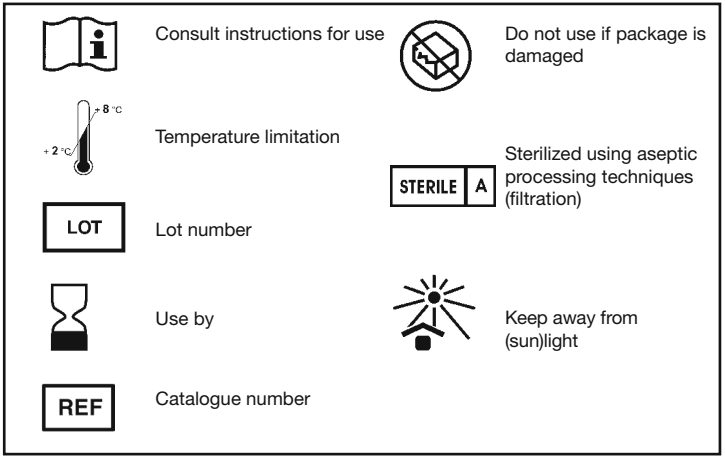
GM501 Hyaluronidase EN

Bovine sourced Hyaluronidase:

- The Pharmaceutical grade hyaluronidase used in this product is sourced from bovine testis. It is certified not to contain any neuronal tissue (Certificate of Suitability/ CEP).
- Hyaluronidase is sourced from animals determined „fit for human consumption“ and originating from countries with „negligible BSE risk“ (Resolution No. 18 „Recognition of the Bovine Spongiform Encephalopathy Risk Status of Member Countries (2014)“, adopted by the OIE).
- According to the „WHO guideline on Transmissible Spongiform Encephalopathies in Relation to Biological and Pharmaceutical Product“, and according to EC directive 2004/C24/03 „Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01) adopted by the Committee for Proprietary Medicinal Products (CPMP) and by the Committee for Proprietary Medicinal Products (CVMP)“, testis material from bovine source is classified as a „Category C: Tissues with no detected infectivity“ product.

Storage instructions and stability:

- The shelf life is 12 months from time of manufacture.
- Store between 2-8°C.
- Do not freeze before use.
- Keep away from (sun)light.
- The product can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C.
- Do not use after expiry date.
- Stable after transport (max. 5 days) at elevated temperature (≤ 37°C)



For technical support:

GYNEMED Medizinprodukte GmbH & Co. KG,
Lübecker Straße 9, 23738 Lensahn - Germany
Phone: +49 (0) 4363 90 32 9-0 **- Fax:** +49 (0) 4363 90 32 9-19
Email: info@gynemed.de **- http:** //www.gynemed.de

Gebrauchsanweisung:GM501_Hyaluronidase:
Gebrauchsanweisung_GM501_Hyaluronidase_EN_Rev03_00.indd
Stand: 2017-03-13

CE 0344