

### SYNBIOS<sup>®</sup> HYALURONIDASE

#### GENERAL INFORMATION ON USE

**SYNBIOS<sup>®</sup> HYALURONIDASE** medium contains 80 IU/ml pharmaceutical grade hyaluronidase from bovine origin, in **SYNBIOS<sup>®</sup> Flushing medium** (HEPES-buffered medium which contains 4.00g/liter human serum albumin). The product is ready for use. Hyaluronidase in **SYNBIOS<sup>®</sup> HYALURONIDASE** is used for denuding or stripping the oocyte of its cumulus and corona cells. Hyaluronidase digests the chemical bonds between the cumulus cells, which makes it easier to remove the cumulus and corona cells mechanically

#### MATERIALS SUPPLIED

10ml of **SYNBIOS<sup>®</sup> HYALURONIDASE**. (Ref: HE10010)

#### MATERIALS REQUIRED BUT NOT SUPPLIED

Test tubes & culture dishes; Oocyte and embryo handling pipettes; Laminar flow/Biological hoods, Stereo & Inverted Microscopes; Incubators, and other ART Lab equipment. Others include: **SYNBIOS<sup>®</sup> culture**, sperm; Gamete, Flush, and PVP media.

#### SPECIFICATIONS AND QUALITY CONTROL

**SYNBIOS<sup>®</sup> HYALURONIDASE** is manufactured according to these specifications:

pH: 7.30 – 7.60 (release criteria under air)

Osmolality: 270 – 290 mOsm/kg

Endotoxin: < 1.00 EU/ml

Sterility: Sterile

Mouse-embryo test: ≥ 80% blastocysts after 96 hours culture (exposure at zygote stage)

Use of Ph Eur or USP grade products if applicable

A certificate of analysis and MSDS are available upon request

#### STORAGE AND CONSERVATION

**SYNBIOS<sup>®</sup> HYALURONIDASE** is stable after transport (max. 5 days) at elevated temperature (≤ 37°C). Store Hyaluronidase in **SYNBIOS<sup>®</sup> Flushing medium** between 2-8°C. Do not freeze before use. Keep the product in original packaging and shield from light/ sun. The product can be used for 7 days after opening when sterile conditions are maintained and between 2-8°C. Do not use after expiry date. Content cannot be resterilized after opening.

#### CAUTION

**Hyaluronidase exposed to the elements or above 8°C for >8 hours may be unfit for use for human ART treatment due to possible formation of toxic free radicals and products of putrefaction.**

#### DISCLAIMER:

This product is manufactured in compliance with the GMP quality standards. Every effort has been taken to ensure quality of the product. We have no control over the products during transport. Shippers are aware of cold-chain protocol. Product could be damaged for any reason during transport. End users must ensure products received are in good condition by internal QC/QA procedures prior to use.

#### WARNINGS AND PRECAUTIONS

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 be totally 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. The above media do not contain antibiotics, always work under strict hygienic conditions (e.g. LAF-bench ISO Class 5) to avoid contamination. Don't use media if liquid is cloudy.

#### BOVINE SOURCED HYALURONIDASE

The pharmaceutical grade hyaluronidase used in this product is derived from bovine testis and is certified with a TSE risk evaluation Certificate of Suitability (CEP). The animals from which the hyaluronidase is derived, are determined fit for human consumption" and originate from countries with "negligible BSE risk", as determined Resolution "Recognition of the Bovine Spongiform Encephalopathy Risk Status of Member Countries", adopted by the OIE. According to the WHO guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies (2010), testes from bovine source are classified as Category IC material (i.e. "Tissues with no detected infectivity")

#### INSTRUCTIONS FOR USE

1. Warm **SYNBIOS<sup>®</sup> HYALURONIDASE** medium to 37°C.
2. Prepare a dish containing 1 droplet of **SYNBIOS<sup>®</sup> HYALURONIDASE medium** (100 µL) and 3-5 droplets (100µL) of **SYNBIOS<sup>®</sup> Flushing medium** for oocyte washing (all under light paraffin oil e.g. **SYNBIOS<sup>®</sup> Mineral Oil**).

3. Place oocytes **SYNBIOS<sup>®</sup> HYALURONIDASE** medium (up to 5 oocytes maximum) for about 30 seconds.

4. Using a oocyte handling pipet ( 170 microns) transfer the partially denuded oocytes into the first washing droplet.

5. Remove the corona by gently pipetting the oocytes with denuding pipet (130-140 microns).

6. Use the other droplets to further wash the denuded oocytes.

7. Transfer denuded oocytes to equilibrated and warmed **SYNBIOS<sup>®</sup> EMBRYO CULTURE MEDIUM** and hold in this medium in the CO<sub>2</sub> incubator until the ICSI procedure.

**NOTE:** Do not incubate in a CO<sub>2</sub> incubator. Hyaluronidase in **SYNBIOS<sup>®</sup> HYALURONIDASE** medium is HEPES-buffered. Incubation in a CO<sub>2</sub> incubator will lower the pH below 7 and as a result the oocytes may be damaged.

**Good Laboratory Practices**

ART Lab personnel are urged to adhere to Good Laboratory Practices (GLP) for optimizing the treatment outcome. Dishes must not be out of incubator for more than 3 mins at any one time.

**Note: This product is classified as a medical device. US Federal Law restricts its sale by or on order of a physician (Rx only).**

Custom-produced under GMP quality standards

For ANDROCRYOGENICS, Malaysia

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**SYNBIOS<sup>®</sup>  
HYALURONIDASE  
MEDIUM**

**20 Years of Research  
Ensures Optimal Performance**

**SYNBIOS<sup>®</sup> MEDIA**  
Safety. Performance. Innovation

**GMP-Manufactured**

HYALURONIDASE for oocyte denudation process.

**Ref: 10 mL HE10010**

SYNBIOS<sup>®</sup> HYALURONIDASE is sterilized by sterile filtration.