



## Instructions for the Use of HSA

(Catalogue Numbers: GHSA-125)

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### PRECAUTIONS AND WARNINGS

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1. **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
2. **Caution:** The user should read and understand the Instructions for Use, Precautions and Warnings, and be trained in the correct procedure before using HSA for use as a protein supplement for culture media and other solutions that are used in assisted reproductive procedures.
3. Not to be used for injection.
4. Do not resterilize.
5. Do not use the product if:
  - the product packaging appears damaged or if the seal is broken
  - the expiry date has been exceeded
  - the product becomes discolored, cloudy, or shows evidence of particulate matter
6. This product contains human serum albumin, a derivative of human blood. The human serum albumin used in the preparation of this product has been heated at 60°C for ten hours.

**Caution:** 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 virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes. It is strongly recommended that every time that HSA is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

7. To avoid problems with contamination, practice aseptic techniques.
8. Each vial of HSA is intended for **single use only**. Discard any unused product after opening.

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### GENERAL INFORMATION

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#### Indications for Use

For use as a protein supplement for Lifeglobal media used in assisted reproductive procedures.

#### Storage and Shelf Life

Store at 2-8°C and protected from light. One (1) year from the date of manufacture.

#### Disposal Consideration

Treat or dispose of waste material in accordance with all local state/provincial, and national requirements. Dispose with laboratory waste.

#### Composition

HSA consists of human serum albumin from therapeutic-grade source material, as a concentration of 100 mg/ml in a sterile saline solution.
















**QUALITY CONTROL SPECIFICATIONS**

Assay (performed for each batch)	Specification
<b>Physicochemical Tests</b>	
pH	7.2-7.4
Osmolality	265-285 mOsM
<b>Biological Tests</b>	
Endotoxin (LAL)	≤ 1.0 EU/ml
Sterility Test (bacterial and fungal screen, SAL 10 <sup>-3</sup> )	PASS
<b>Biological Assays</b>	
1-cell Mouse Embryo Assay (% expanded blastocysts at 96 h of culture)	≥ 80%

**INSTRUCTIONS FOR USE**

Twenty-four hours prior to the use of media for embryo culture or handling, mix appropriate volumes of medium and HSA (100 mg/ml) in an embryo-safe container to produce the desired concentration of HSA in the mixture. For example, 9.0 ml of medium plus 1.0 ml of HSA (100 mg/ml) will yield a final concentration of 10 mg/ml HSA in the mixture. For all bicarbonate-buffered media, pre-incubate drops of the mixture under the appropriate CO<sub>2</sub> concentration, for a minimum of 4 hours prior to use. Mixtures of HEPES-buffered media should not be exposed to CO<sub>2</sub>.

**SYMBOLS**

	<b>RX Only</b>				
Sterile Using Aseptic Processing Techniques	By Prescription Only	Catalogue Number	Batch Code	Consult Instructions For Use	Manufacturer
					
Keep Away From Sunlight	Temperature Limitation	Authorized Representative in the European Community	Use By	Do Not Reuse	GS1 DataMatrix Barcode
					
Do Not Resterilize	European Conformance (notified body)	Do Not Use if Package is Damaged			