Gx-MOPS™ PLUS

Vitrolife

Indication for use

Medium for handling and manipulating oocytes and embryos in ambient atmosphere.

Contraindications

Gx-MOPS™ PLUS contains gentamicin and acetylcysteine. Do not use in patients with known hypersensitivity/allergy to any of the components.

Product Description

SUPPLEMENTED WITH HSA.

Gx-MOPS™ PLUS is a MOPS buffered medium containing human serum albumin, acetylcysteine and gentamicin as an antibacterial agent.

Ready to use after equilibration at +37°C and ambient atmosphere.

The summary of safety and clinical performance can be found at www.vitrolife.com

Storage instructions and stability

Store dark at +2 to +8°C.

Gx-MOPS PLUS is stable until the expiry date shown on the container labels and the LOT-specific Certificate of Analysis.

Media bottles can be used for up to two weeks after first opening, use aseptic technique and minimize the time outside the refrigerator. Opening of the bottle shall be limited to the time needed to remove the necessary amount of medium. Discard excess media no later than two weeks after first opening.

Directions for use

The product shall be used by an IVF professional.

The patient target group is an adult or reproductive-age population that undergoes fertility treatment.

Record the opening date on the bottle.

Never place Gx-MOPS PLUS inside a CO_2- incubator or cover it with CO_2-equilibrated oil.

Gx-MOPS PLUS can be used for procedures such as handling and collection of cumulus-oocyte complexes, denudation, ICSI, embryo biopsy or other handling procedures at ambient atmosphere.

The volume of Gx-MOPS PLUS used for preparation depends on the procedure according to laboratory practice.

The pH of Gx-MOPS PLUS is stable in ambient environment. To minimize changes in osmolality, Gx-MOPS PLUS can be covered with oil for ART procedures immediately following preparation. Gx-MOPS PLUS with oil overlay may be used for up to 6 hours after preparation.

If Gx-MOPS PLUS is warmed without oil cover in a non-humidified environment, keep the lid on and use Gx-MOPS PLUS as soon as possible after warming, always within 60 minutes after preparation.

Oocytes or embryos shall not remain in Gx-MOPS PLUS for more than 30 minutes. Immediately following the procedure, transfer oocytes or embryos into the appropriate culture medium, including at least two washing steps to avoid carry-over of MOPS buffer into the medium used for culture.

Specifications

Aseptically filtered	
Mouse Embryo Assay, 1-cell [% embryos developed to expanded blastocyst at 96 hours]	≥80
Bacterial endotoxins (LAL assay) [EU/mL]	< 0.25
pH tested	
Osmolality tested	

LOT specific test results are available on the Certificate of Analysis provided with each delivery.

Precautions

Discard product if bottle integrity is compromised. Do not use Gx-MOPS PLUS if it appears cloudy.

Gx-MOPS PLUS contains human serum albumin.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived 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 methods can offer assurance that products derived from human blood will not transmit infectious agents.

To avoid contamination Vitrolife strongly recommends that media should be opened and used only with aseptic technique.

The risk of reproductive and developmental toxicity for IVF media, including Vitrolife´s IVF media, has not been determined and is uncertain

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Not for injection.

Discard the product according to standard clinical practice for medical hazardous waste when the procedure is finished.

Symbols glossary

Symbol	Title of symbol	Reference and symbol ID.
	Consult instructions for use	*Ref. no: 5.4.3
	Caution	*Ref. no: 5.4.4. Consult Instructions for use for important cautionary information.
	Manufacturer	*Ref no: 5.1.1
	Date of manufacture	*Ref no: 5.1.3
	Use-by date	*Ref no: 5.1.4
LOT	Batch code	*Ref no: 5.1.5
REF	Catalogue number	*Ref no: 5.1.6
STERILE A	Sterilized using aseptic processing techniques	*Ref no: 5.2.2
	Single sterile barrier system	Graphical symbols for use on equipment — Registered symbols (ISO 7000:2019). Ref no: 3707
	Temperature limit	*Ref no: 5.3.7
	Keep away from sunlight (light sources)	*Ref no: 5.3.2
	Contains a medicinal substance	Graphical symbols for use on equipment — Registered symbols (ISO 7000:2019). Ref no: 3702
	Contains human blood or plasma derivatives	Graphical symbols for use on equipment — Registered symbols (ISO 7000:2019). Ref no: 3701
MD	Medical Device	Indicates that the device is a medical device as defined in Regulation (EU) 2017/745

*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied (ISO 15223-1:2016).

Caution: Federal (US) law restricts this device to sale by or on the order of a physician or practitioner trained in its use (Rx only).

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Patent No.
Patents pending

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