

# CorneaMax®

## STORAGE MEDIUM

Ref: CMXSTO01F

### INTRODUCTION

A corneal transplant is usually carried out in three stages.

Corneas are sampled by *in situ* excision of the cornea (also known as keratectomy). After restoring the donor's tegumen by means of an eye patch (Ref: EYCEY00), the graft is placed in a transfer medium, CorneaPrepII® (Ref.: CMXSTA01F) CorneaPrepII® allow a room temperature transport up to 6 days however everything must be done to place the cornea between 31° to 34°C as soon as possible. The use of secure caps (Ref: EYEBCH03) ensures that neither the container nor its contents are tampered with during transport.

❑ **Registered tissue banks are responsible for storing the corneas. When the eye bank receives the corneal graft, in its transfer medium, the cornea is placed in a storage medium, CorneaMax® (Ref: CMXSTO01F) and stored at +31°C ± 1°C for the quarantine period (no more than 30 days). During this period, all the statutory analyses are carried out. Storage of the cornea leads to reversible opacification of the cornea.**

❑ After analysing the graft and selecting the recipient, the cornea is placed in a deturgescence medium CorneaJet® (Ref: CMXREL01F). The cornea must be kept in this medium for at least 24 hours to ensure transparency. The medium can then be used to transport the graft within 4 days (including the 24 hours of deturgescence). During transport at ambient temperature, the use of secure caps (Ref: EYEBCH00) ensures that neither the container nor its contents are tampered with.

Laboratoires Eurobio can provide three media, each particularly suitable for one of the above stages:

- CorneaPrepII® for sampling and transport,
- CorneaMax® for storage,
- CorneaJet® for the deturgescence and transfer of corneal grafts.

### PRESENTATION

CorneaMax® is supplied in a 120 ml white glass bottle containing 100 ml of medium.

To guarantee that the containers have not been tampered with, they are sealed with tamper-proof caps.

**Ref: CMXSTO01F-1C including:**

- ❑ **10 x 100 ml bottles of CorneaMax®**
- ❑ **Certificates of analysis and technical specifications.**

***Remember to order additional caps.***

✎ Three types of additional sterile caps in individual "peel-off" sachets should be ordered separately:

- ❑ Ref. EYEBCH00-F3 : 10 sterile tamper-proof caps for CorneaMax®.
- ❑ Ref. EYEBCH01-F3 : 10 sterile caps for suspension
- ❑ Ref. EYEBCH02-F3 : 10 sterile caps for medium sampling.

### COMPOSITION / PROPERTIES

• Cell culture medium (registered formulation) including:

- Essential and non-essential amino acids.
- Australian irradiated foetal calf serum.
- Vitamins and electrolytes.
- Penicillin – Streptomycin.
- HEPES buffer and bicarbonate.
- Phenol red.

- pH: 7.25 ± 0.25.
- Osmolarity = 320 ± 20 mOsm/kg H<sub>2</sub>O
- Controlled level of endotoxins
- Free from mycoplasmas
- Medium sterilised by aseptic filtration

### INDICATIONS FOR USE

- ❑ CorneaMax® sampling medium is ready to use.
- ❑ The medium should be thawed gradually: at 4°C, at ambient temperature or in a bain-marie at 37°C.
- ❑ When the sample is received from the laboratory, remove the cornea from the transfer medium (CorneaPrepII®) and place in the storage medium (CorneaMax®). The transfer should take place under a

laminar flow hood and all the usual precautions for cell cultures should be taken.

□ Once the cornea has been placed in CorneaMax<sup>®</sup>, close the container with any of the three types of sterile cap in accordance with your normal practice (see the technical specifications of the caps).

□ The graft is stored in this medium at +31°C ± 1°C for the quarantine period (no more than 30 days). During this period, all the statutory analyses are carried out. Storage of the cornea in this medium leads to reversible opacification.

□ The medium contains a cherry red indicator. If the colour turns yellow or deep purple (change in pH) or if any turbidity appears, we recommend not to use the grafts stored in the medium.

## RECOMMENDATIONS

□ CorneaMax<sup>®</sup> should only be used for *in vitro* purposes.

□ CorneaMax<sup>®</sup> should only be used by professionals with experience in organ removal.

□ The medium must be discarded after use, in accordance with the usual procedures for the disposal of biological waste.

□ The medium contains antibiotics i.e. penicillin and streptomycin.

□ The medium contains ingredients of bovine origin. The source of supply has been inspected and controlled free of Transmissible Spongiform Encephalopathy.

## CONTRA-INDICATIONS

□ CorneaMax<sup>®</sup> storage medium is ready for use. It must not be repackaged, portioned or diluted. The 100 ml volume corresponds to the quantity required to store a cornea for 30 days.

□ The medium must be thawed gradually. Temperatures in excess of 37° C must be avoided.

□ Do not re-freeze thawed medium.

□ Do not insert a foreign body (e.g. suture) between the neck and the cap of the containers, or else these will no longer be sealed.

## STORAGE

CorneaMax<sup>®</sup> has been deep frozen at -20°C and is supplied in isothermic packaging containing dry ice.

**Upon receipt of the product, check that the containers are deep frozen and store at -15/-22°C.**

Stability: see the Use By date on the label.

Thawing: at ambient temperature or in a bain-marie at 37°C.

Stability after thawing: CorneaMax<sup>®</sup> can be kept at 4°C for no more than 5 days after opening.

## NEVER REFREEZE ANY MEDIUM AFTER THAWING

## REFERENCES IN THE CORNEA RANGE

Ref	Description	Packaging
CMXSTA01F-AR	CorneaPrepl <sup>®</sup>	10 x 60 ml 10 eye patches 10 caps
EYEBCH03-F3	Tamper-proof cap for CorneaPrepl <sup>®</sup>	10 caps
EYECEY00-F3	Eye patch	10 caps
CMXSTO01F-1C	CorneaMax <sup>®</sup>	10 x 100 ml
EYEBCH00-F3	Tamper-proof cap for CorneaMax <sup>®</sup> and CorneaJet <sup>®</sup>	10 caps
EYEBCH01-F3	Suspension cap for CorneaMax <sup>®</sup>	10 caps
EYEBCH02-F3	Sampling cap for CorneaMax <sup>®</sup>	10 caps
CMXREL01F-1O	CorneaJet <sup>®</sup>	10 x 50 ml 10 caps
EAUCOL00-C8	Trypan Blue	10 x 2 ml

## BIBLIOGRAPHY

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