

# KERASAVE

MEDIUM FOR CORNEAL STORAGE AT 4°C  
12 VIAL PACK + 1 BLISTER PACK OF 12 TABLETS + 12 DONOR EYE CAPS

## STORAGE AT 4°C + COSMETIC RECONSTRUCTION

	KERASAVE SOLUTION	AMPHOTERICIN B TABLET	DEC
<b>Ingredients</b>			
	MEM balanced salt solution	soluble amphotericin B	polyacrilate
	gentamicin	excipients	
	streptomycin		
	dextran		
	bicarbonate		
<b>Form</b>	sterile liquid	sterile tablet	solid
<b>Size</b>	20 ml	42.5 mg	2.8x2.4 cm (L x w)
<b>Chemical-Physical Parameters</b>			
Hydrogenionic activity	7.20 - 7.60 pH units	not applicable	not applicable
Osmolality	255 - 345 mOsm/kg	not applicable	
Gentamicin content	100 - 110 µg s.s./ml	not applicable	
Streptomycin content	200 - 220 µg s.s./ml	not applicable	
Amphotericin B content	not applicable	2.25 - 2.88 µg s.s/ml in solution)	
Dissolution time in KERASAVE solution	not applicable	about 20 min under stirring	
<b>Bacterial endotoxins</b>	< 0.5 EU/ml		not applicable
<b>Sterilization</b>	aseptic filtration and filling according to EN 556-2 and EN 13408-1	gamma rays according to EN 556-1 and EN ISO 11137-1	non-sterile
<b>Packaging</b>	20 ml vial	blister pack of 12 tablets	pouch
<b>Storage temperature</b>	+2°C / +8°C	+2°C / +8°C	not applicable
<b>Expiry date</b>	24 months	24 months	60 months
<b>Intended use</b>	corneal storage at +4°C	antifungal agent	cosmetic reconstruction of donor eye
<b>Temperature of actual use</b>	+2°C / +8°C		
<b>Duration of actual use</b>	up to 14 days		not applicable
<b>Class</b>	medical device	medical device	not applicable
<b>CND code</b>	Q020299		not applicable
<b>Medical device class</b>	IIa		not applicable
<b>CE mark</b>	CE0546		not applicable

KERASAVE is a corneal storage medium containing antibiotics and an antifungal agent (Amphotericin B). The device consists of a solution and a tablet containing Amphotericin B to be dissolved in the liquid before the introduction of the tissue.

The reconstituted solution is a medium that enables the hydration of the cornea and slows down the cell degeneration process thanks to the temperature of 4°C.

The combined presence of an antifungal agent and antibiotics ensures the microbiological quality of the storage environment.

**Ref.:** KER 002-00

**Contents:**

- ▶ 12 20ml vial pack
- ▶ 1 blister pack of 12 tablets
- ▶ 12 DEC
- ▶ 24 labels for product traceability
- ▶ 1 pH color control scale
- ▶ 1 package insert

**GS1-128 barcode**

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