ALCHIMIA

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
Ingredients			
	MEM balanced salt solution	soluble amphotericin B	polyacrilate
	gentamicin	excipients	
	streptomycin		
	dextran		
	bicarbonate		
Form	sterile liquid	sterile tablet	solid
Size	20 ml	42.5 mg	2.8x2.4 cm (L x w)
Chemical-Physical Parameters			
Hydrogenionic activity	7.20 - 7.60 pH units	not applicable	not applicable
Osmolality	255 - 345 mOsm/kg	not applicable	
Gentamicin content	100 - 110 µg/ml	not applicable	
Streptomycin content	200 - 220 µg/ml	not applicable	
Amphotericin B content	not applicable	45 - 57.5 µg/tablet (2.25 - 2.88 µg/ml in KERASAVE solution)	
Dissolution time in KERASAVE solution	not applicable	about 20 min under stirring	
Bacterial endotoxins	< 0.5 EU/ml		not applicable
Sterilization	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
Packaging	20 ml vial	blister pack of 12 tablets	pouch
Storage temperature	+2°C / +8°C	+2°C / +8°C	not applicable
Expiry date	24 months	24 months	60 months
Intended use	corneal storage at +4°C	antifungal agent	cosmetic reconstruction of donor eye
Temperature of actual use	+2°C / +8°C		
Duration of actual use	up to 14 days		not applicable
Class	medical device	medical device	not applicable
CND code	Q020299		not applicable
Medical device class	IIa		not applicable
CE mark	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.
The optically clear vial bottom allows to evaluate cornea by specular microscopes (e.g. Konan, Hailabs) with no need to transfer it to another container, thus reducing contamination.

Ref.: KER 002-00

Contents:

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

GS1-128 barcode

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