

LINOVERA® Scar Repair

TECHNICAL FILE



ADMINISTRATIVE INFORMATION

HEAD OFFICE ADDRESS	B. Braun Medical S.A. Carretera de Terrassa, 121. 08191 Rubi. Barcelona, Spain
SBA & PRODUCT MANAGER	Wound Management, Louis vanden Schrieck
SAFETY OFFICER MEDICAL DEVICES	Stephan Krause
LAST UPDATE	14/05/2021

DESCRIPTION, COMPOSITION AND PROPERTIES OF THE DEVICE

COMMON NAME (FAMILY)	Skin prevention (567)
TRADE NAME	Linovera® Scar Repair
REFERENCES	450450
GMDN CODE	N/A
MEDICAL CLASS	N/A, Cosmetic product

DESCRIPTION OF THE DEVICE

Linovera® Scar Repair has an innovative and exclusive formulation of Hyaluronic acid, Asian centella and Syricalm® which is a combination of natural extracts. The prolonged use of Linovera® Scar Repair helps the processes of elasticity improvement and natural colour of the healed tissue.

COMPOSITION OF THE DEVICE	Components	Function
	Aqua (Water)	Solvent
	Propylene Glycol	Moisturising, Skin conditioning, Solvent, Viscosity control
	Hydroxyethyl Acrylate, Sodium Acryloyldimethyl Taurate Copolymer	Stabilizer, Viscosity control
	Hyaluronic Acid	Antistatic, Wetting, Moisturising, Skin conditioning
	Sodium Benzoate	Preservative
	Asiaticoside	Antioxidant, Perfume, Skin conditioning
	Phragmites Karka Extract	Skin conditioning
	Poria Cocos Extract	Skin conditioning
	Asiatic Acid	Skin conditioning, Stabilizer
	Madecassic Acid	Skin conditioning
PROPERTIES OF THE DEVICE	Innovative and exclusive gel. Made of Hyaluronic acid, Asian centella and Syricalm® which is a combination of natural extracts.	

KEY DRIVERS & INDICATIONS	
KEY DRIVERS	Hydrate and improve skin elasticity Help to soften and flatten scars
INDICATIONS	Linovera® Scar Repair is indicated for helping the processes of elasticity improvement and natural colour of the healed tissue.

STERILIZATION PROCESS: REPORT	
STERILE MD: YES/NO	No
STERILIZATION METHOD	N/A

CONSERVATION AND STORAGE CONDITIONS	
STORAGE CONDITIONS	5° - 25°C. Store Linovera® Scar Repair at room temperature, away from direct sunlight and out of humidity. Dispose of the product in accordance with local regulations.
TRANSPORT CONDITIONS	5° - 25° C. Store Linovera® Scar Repair at room temperature, away from direct sunlight and out of humidity.
SHELF LIFE	3 years from date of manufacture

SAFETY IN USE

TECHNICAL: MRI, X-RAY DETECTABLE

N/A

ORGANIC

Latex, DEHP, phthalate free

BIOCOMPATIBILITY

Doc References n°02/TC-PTS_011_14-002

STANDARDS & REQUIREMENTS

Regulation (EC) No 1223/2009

Directive 97/1/CEE

96/335/EC: Commission Decision

ISO 22716:2007

RECOMMENDED USE

IFU: YES/NO

Yes, presence of IFU 488007_0917

PRECAUTION OF USE

Precaution of use: Do not apply Linovera® Scar Repair over damaged or not completely healed wounds.

CONTRAINDICATION

Contraindication: Do not use Linovera® Scar Repair in case of a known sensitivity to any of its components.

ADDITIONAL PRODUCT INFORMATION

REUSABLE/SINGLE USE DEVICE

Reusable.

It is recommended to use a soft silicone bandage (for example Askina® Scar Repair) to protect the skin from UV rays and improve the effect of the product. Hypoallergenic product. Tested under dermatological control.

PACKAGING & REFERENCES

Transport box for dispatching and additional protection against damage during transportation.

PACKAGING & PRODUCT LABEL



REFERENCES

Reference	Description	Size	Quantity per box
450450	Linovera® Scar Repair	15 g	20