

# LINOVERA®

## 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	21/04/2021

### DESCRIPTION, COMPOSITION AND PROPERTIES OF THE DEVICE

COMMON NAME (FAMILY)	Skin prevention (567)
TRADE NAME	Linovera®
REFERENCES (SPECIFIC REFERENCES BY COUNTRY)	450336, 491751, 492742, 492795, 492796, 492797, 492808, 492831, 492832, 492833, 480060, 480080, 480082, 467933, 468155, 468156, 468157, 468157FR, 488354, 492736, 492737, 492738, 492739, 492740, 492741, 492810, 492972, 450081
GMDN CODE	57966 – Pressure ulcer topical dressing
MEDICAL CLASS	Ila

### DESCRIPTION OF THE DEVICE

Hyperoxygenated essential fatty acids (HOFA) present in the composition of Linovera® favor blood microcirculation, reducing the risk of ischemia and facilitating the renewal of epidermal cells, increasing the resistance of the skin against the agents that cause pressure ulcers. At the same time they protect against friction, reduce skin fragility and prevent dehydration of the skin.

In addition, thanks to their antioxidant activity, they reduce the damage caused by free radicals. Linovera® also contains Aloe Barbadensis and Asian Centella. Aloe Barbadensis, also known as Aloe Vera, helps condition the skin and acts as emollient and humectant. Asian Centella also acts as a skin conditioner and has a toning and soothing effect on the skin.

COMPOSITION OF THE DEVICE	Components	Function
	Sunflower Hydroxylated Fatty Acids	Emollient
	Aloe Barbadensis	Skin conditioning, Emollient, Humectant
	Rosemary Essence	Organoleptic characteristics
	Asian Centella	Skin conditioning, toning and soothing effect on the skin.

PROPERTIES OF THE DEVICE	Hydroxylated fatty acids from sunflower oil and vegetable extracts.
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### KEY DRIVERS & INDICATIONS

KEY DRIVERS	Increase blood microcirculation, reducing the risk of ischemia
	Facilitate the renewal of epidermal cells
	Enhance the cellular cohesion of the epidermis
	Increase the resistance of the skin against the causative agents of pressure ulcer
	Prevent skin dehydration
	Protect against friction
	Reduce skin fragility
	Decrease the effect of free radical

INDICATIONS	Linovera® is indicated for the prevention and treatment of stage I pressure ulcers.
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### STERILIZATION PROCESS: REPORT

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

### CONSERVATION AND STORAGE CONDITIONS

STORAGE CONDITIONS	5° - 25°C. Do not cool. Do not freeze. Dispose of the product in accordance with local regulations.
TRANSPORT CONDITIONS	5° - 25°C. Do not cool. Do not freeze.
SHELF LIFE	2 years from date of manufacture

## SAFETY IN USE

TECHNICAL: MRI, X-RAY DETECTABLE

N/A

ORGANIC

DEHP, phthalate free

BIOCOMPATIBILITY

Doc References Linovera IIa DTP-6.2.AN.1

## STANDARDS & REQUIREMENTS

Council Directive 93/42/EEC

UNE-EN ISO 13485:2018

UNE-EN ISO 14971:2012

UNE EN ISO 14698-1: 2004

UNE-EN ISO 14644-2:2016

UNE-EN ISO 1041:2009+A1:2014

UNE-EN ISO 15223-1:2016

UNE-EN ISO 10993-1:2018

MEDDEV 2.7.1. Rev.4

ICH Guideline Q1A (R2)

European Pharmacopeia

## RECOMMENDED USE

Yes, presence of IFU Linovera\_IIa DTP-2.2.AN.1

IFU: YES/NO

PRECAUTION OF USE

CONTRAINDICATION

Precaution of use: Store the product in the original pack. Protect the container from direct sunlight. Wash your hands before and after using the product. The use of gloves is recommended. External use. Do not ingest. Avoid contact with the eyes. The product is indicated for adults. Do not use after the expiry date indicated in the bottle and the box.

Contraindication: Do not use in case of known hyper sensibility to any of the ingredients exists. Adverse reactions: Cutaneous manifestations may appear in patients allergic to any of the components. In principle, they are not serious and cease when the application of the product is interrupted or with the use of antihistamines and/or corticoids.

## ADDITIONAL PRODUCT INFORMATION

REUSABLE/SINGLE USE DEVICE

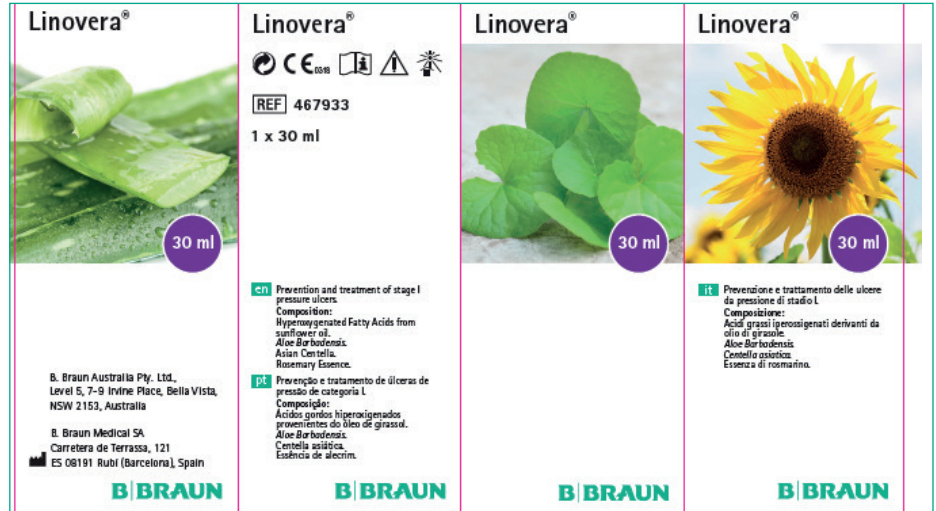
Reusable.

Use in combination with Askina® Heel for optimal protection for non-broken skin of the heel area against pressure ulcers.

## PACKAGING & REFERENCES

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

### PACKAGING & PRODUCT LABEL



### REFERENCES

Reference	Description	Size	Quantity per box
Specific references by country	Linovera®	10 ml	10
480060	Linovera®	20 ml	10
Specific references by country	Linovera®	30 ml	1
450081	Linovera®	50 ml	10

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