

LINOVERA® EMULSION

TECHNICAL FILE



ADMINISTRATIVE INFORMATION

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LAST UPDATE	21/04/2021

DESCRIPTION, COMPOSITION AND PROPERTIES OF THE DEVICE

COMMON NAME (FAMILY)	Skin prevention (567)
TRADE NAME	Linovera® Emulsion
REFERENCES (SPECIFIC REFERENCES BY COUNTRY)	451078, 492799, 492800, 492801, 492802, 492803, 492804, 492811, 492973, 492974, 492976, 492743, 492744, 492745, 492805, 492806, 492807, 492809, 492976, 492977
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® emulsion, 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® Emulsion also contains Aloe Barbadensis, Asian Centella and Ginkgo Biloba. These three ingredients complete the action of the HOFA as a skin conditioning. Aloe Barbadensis, also known as Aloe Vera, acts as emollient and humectant and Asian Centella functions as skin tonic and soothing agent.

COMPOSITION OF THE DEVICE	
Components	Function
Sunflower Hydroxylated Fatty Acids	Emollient
Aloe Barbadensis	Skin conditioning, Emollient, Humectant
Asian Centella	Skin conditioning, Skin tonic, Soothing agent
Rosemary Essence	Organoleptic characteristics
Base F2230	Emulsifier agent
Isopropyl myristate	Emollient
Glycerin	Hygroscopic agent
Sodium chloride	Stabilizer
Ginkgo biloba	Skin conditioning
Purified water	Emulsion vehicle

PROPERTIES OF THE DEVICE	
	Hydroxylated fatty acids from sunflower oil and vegetable extracts.

KEY DRIVERS & INDICATIONS	
KEY DRIVERS	<ul style="list-style-type: none"> 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 radicals
INDICATIONS	Linovera® Emulsion is indicated for prevention and treatment of vascular ulcers, diabetic foot ulcers and stage I pressure ulcers.

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 Emulsion Ila 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 492987_0220

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 hypersensitivity 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.

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® Emulsion	50 ml	1
Specific references by country	Linovera® Emulsion	100 ml	1

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