OLEOABRAX® - LEAFLET

OLEOABRAX®

Hydrogel

DESCRIPTION

OLEOABRAX® is a medical device presented as hydrogel based on Fucocert® (polysaccharide) and glycerine as moisturizers, as well as *Olea europaea* leaf extract, included because of its antioxidant properties. The presence of Carbopol 980® provides an isolating and protective barrier on the wound. The combination of these components, together with the capability to reduce the alkalinity through its slightly acidic pH, gives OLEOABRAX® the ability to modulate the environment of the cutaneous wounds, thus promoting and speeding up the healing process.

INTENDED USE

OLEOABRAX® is intended to the healing of wounds of partial thickness such as abrasions, excoriations, superficial burns, small scratches, aesthetic superficial treatments, little cuts, etc….

PRESENTATION

Carton box containing 1 aluminium tube of 30 g.

COMPOSITION

Each tube contains: 2 mg/g of Fucocert®, 250 mg/g of Glycerine, 13 mg/g of Carbopol 980®, 1 mg/g of *Olea europaea* leaf extract, 20 mg/g of Geogard Ultra®, 1 mg/g of disodium EDTA, 20 mg/g of Trietanolamine and purified water q.s.

INSTRUCTIONS FOR USE

- Before the application of the product clean the wound and its edges with an appropriate cleansing solution and dry thoroughly.
- Unscrew the tube cap.
- Avoiding the contact of the orifice of the tube with the lesion.
- Gently press the tube and apply a 2-3 mm thin layer over the abraded area, without rubbing.
- Cover the area with a secondary dressing, if required.
- Once the secondary dressing is applied, remove any excess of product from the surrounding area.

DOSAGE

OLEOABRAX® is intended to be used in children and adults. It can be used throughout the whole healing process. It is recommended to be used one or two times per day or coinciding with the regular cleaning of the wound and/or with the change of secondary dressing, if any, aiming to facilitate a favourable environment for the healing.
OLEOABRAX® is a multidose product: the content of the same tube can be used for several applications.

WARNINGS AND PRECAUTIONS

- This medical device is not a pharmacological treatment. It can be administered concomitantly with another treatment prescribed by a healthcare professional, if needed.
- The safety and efficacy of OLEOABRAX® has not yet been stablished in pregnant women, during breastfeeding period. Therefore, the use of OLEOABRAX® in this patient group should be performed under the supervision of a healthcare professional.

- Do not use the medical device after the expiry date printed on the package.
- Once opened, do not use after 6 months.
- It can be used on lesions with clinical signs of infection, under a physician supervision.
- Do not apply the gel (or remove it if it has been applied) in the event of a change in colour or bad odour.
- Do not use the medical device if the tube and/or the cap are opened or damaged.
- Do not store above 25ºC. Do not freeze.
- For topical use only. Not for oral use. Product applications close to the eyes require extreme care.
- In case of any reaction in the application area, or any adverse event, stop usage and consult your physician.
- Keep this medical device out of sight and reach of children.
- Any serious incident that has occurred using the medical device should be reported to the manufacturer and the local competent authority.

CONTRAINDICATIONS

OLEOABRAX® must not be used in patients with known hypersensitivity to any component listed in the composition of the product.

SIDE EFFECTS

No relevant side effects related to the use of OLEOABRAX® have been reported in clinical studies.

A summary of safety and clinical performance is available in the manufacturer website and in the European database on medical devices (Eudamed - https://ec.europa.eu/tools/eudamed), where it is linked to the Basic UDI-DI of OLEOABRAX® (843659383OLA923KZ)

INTERACTIONS

No relevant interactions related to the use of OLEOABRAX® have been reported.

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MEANING OF THE SYMBOLS USED

SYMBOL	TITLE	DESCRIPTION OF SYMBOL
	Manufacturer	Indicates the medical device manufacturer, as defined in Medical Device Regulation 2017/745.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for variety reasons, be presented on the medical device itself.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed, in this special case between 2°C and 25°C.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Medical device	Indicates that the product is a medical device.
	Unique device identifier	Indicates carrier that contains unique device identifier information
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.