

INSTRUCTIONS FOR USE

FISH-SKIN GRAFT FOR WOUND MANAGEMENT

INTENDED USE

Kerecis Omega 3 MariGen is indicated for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Draining Wounds

CAUTION

Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner. These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

CONTRAINDICATIONS

Kerecis Omega3 MariGen is derived from a fish source and should not be used in patients with a known allergy or other sensitivity to fish material.

PRECAUTIONS

- Remove most of necrotic tissue prior to device application.
- Remove exudate and control bleeding prior to device application.
- Do not reuse or re-sterilize.
- Discard unused portions of device.
- Do not use after printed expiration date.
- Sterile if package is unopened and undamaged.
- Do not use device if package seal has been broken or if handling has caused damage or contamination.
- Do not use in case of known fish allergies.

POTENTIAL COMPLICATIONS

The following complications are possible. If any of these conditions occur, the device should be removed.

- Infection
- Chronic inflammation (Initial application of wound dressings may be associated with transient, mild, localized inflammation)
- Allergic reaction
- Excessive redness, pain, swelling, or blistering

STORAGE

This device should be stored in a clean, dry location at room temperature.

STERILIZATION

This device has been sterilized using ethylene oxide.

SUGGESTED INSTRUCTIONS FOR USING Kerecis Omega3 MariGen

The following recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. Always handle Kerecis Omega3 MariGen in an aseptic manner.

First application

1. When applying Kerecis Omega3 MariGen for the first time, clean the wound bed by removing necrotic tissue to obtain a fresh tissue surface. Irrigate to remove debris and exudates. The sheet can be applied to lightly bleeding wound bed.
2. Remove the Kerecis Omega3 MariGen product from the pouch using aseptic technique
3. Fit the product roughly to the size of the area to be covered and pre-hydrate in NaCl solution.
4. Apply product directly into the wound, making sure that the sheet does not overlap the wound edges
5. More than one product may be necessary for complete coverage. Overlap product edges slightly to assure coverage of the entire wound.
6. Apply an appropriate secondary, non-adherent wound dressing to maintain a moist wound environment.

Follow-up applications

After starting treatment with Kerecis Omega3 MariGen, the wound should be checked regularly to ensure that the cover dressing is maintaining a sufficient moist wound environment and if a re-application of Kerecis Omega3 MariGen is needed.

1. Inspect wound every two days. The duration between inspections may be extended up to seven days as healing progresses.
2. Insert a new Kerecis Omega3 MariGen product into the wound if the previously applied product has been absorbed and is no longer visible.
3. Change the cover dressing as needed to maintain a moist, clean wound area.

As wound healing occurs, redness and swelling of wound edges will decrease and the level of exudate will be reduced. These are signs of wound healing and are often seen before epithelization is obvious. Make sure to use an appropriate type of cover wound dressing at all times to maintain a moist, clean wound area.

Should you suspect any adverse reaction from this product please report it to the e-mail adversereactions@kerecis.com leaving a phone number and e-mail address. Adverse reactions might also be subject to mandatory reporting to the authorities. Please submit the data on the package or pouch i.e. "lot number" and "use before" date.

SYMBOLS FROM PRODUCT LABEL



keep away from sunlight



keep dry



does not contain or have the presence of natural rubber latex



upper limit of temperature, 77°F, 25°C



consult instructions for use



do not use if package is damaged



do not reuse



sterilized with ethylene oxide

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