



Rx Only

Caution: Federal law (USA) restricts this product to sale by or on the order of a physician (or properly licensed healthcare professional).

COLLAGEN MATRIX

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

Omeza® Collagen Matrix is a wound care matrix comprised of hydrolyzed fish collagen infused with cod liver oil, which acts as an anhydrous skin protectant. When applied to a wound surface, the matrix is naturally incorporated into the wound over time. Omeza® Collagen Matrix is designed for intimate contact with both regular and irregular wound beds, to provide a conducive environment for the patient's natural wound healing process.

Contains: Fish collagen, cod liver oil, medium chain triglyceride oil, coconut oil, hemp seed oil, triethyl citrate, ethyl linoleate, caprylic acid, red palm concentrate, monolaurin, cetyl esters NF, beeswax, ascorbyl palmitate, sea salt

Omeza Collagen Matrix is supplied in a sterile single use vial.

INDICATIONS FOR USE

Omeza® Collagen Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, superficial partial thickness burns, skin tears) and draining wounds. **The product is intended for one-time use.**

CONTRAINDICATIONS

- This product should not be used in patients with known sensitivity to fish collagen or cod liver oil.
- The product is not indicated for use in third degree burns

PRECAUTIONS

- Each unit of Omeza Collagen Matrix is for single use. Discard all opened and unused portions of Matrix.
- Vial contents are sterile if the vial is unopened and undamaged. Do not use if the vial is broken. Do not re-sterilize.
- Discard product if mishandling has caused possible damage or contamination.
- Excessive exudate, bleeding, acute swelling, and infection should be controlled before Omeza® Collagen Matrix is applied. Debridement or excision must be done thoroughly to remove any remaining necrotic tissue that may cause infection.
- The following complications are possible with the use of wound management products: infection, chronic inflammation (initial application of wound dressings may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain, or swelling. If any of these conditions occur, the product should be removed.

DIRECTIONS FOR USE

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.

Dosage

- Do not apply more than 2 vials in one day
- Do not apply more than 4 vials in one week

Initial application

1. Always handle Omeza® Collagen Matrix using aseptic techniques. Only vial content is sterile.
2. Prior to application of Omeza Collagen Matrix, prepare the wound bed using standard methods to ensure wound is free of debris and necrotic tissue. If necessary, surgically debride the wound to ensure the wound edges contain viable tissue.
3. Snap or cut off the tip of the Omeza Collagen Matrix vial.
4. Slowly squeeze vial to apply either directly to the wound bed in stripes, or onto a suitable applicator (e.g. a tongue depressor). Use the applicator to distribute product evenly across the wound bed so that it is uniformly applied at an approximate thickness of a nickel (~1.95mm).

(OVER)

5. After application, cover with an appropriate dressing to maintain matrix adherence and protect the wound area. The optimum dressing is determined by wound location, size, depth, and volume of exudate.

Follow-up application

1. Duration of treatment and reapplication frequency is determined by the physician and will depend on the condition of the patient as well as the level of wound exudate.
2. Reapply when Omeza® Collagen Matrix has been naturally incorporated into the wound bed or as directed by a wound care professional.
3. Remove the dressing from the wound bed gently.
4. Cleanse the wound area and prepare the wound bed prior to application.
5. Distribute product evenly across the wound bed so that it is uniformly applied at an approximate thickness of a nickel (~1.95mm).
6. Cover with an appropriate dressing to maintain matrix adherence and protect the wound area.
7. Change the dressing based on physician assessment of patient's individual needs and as consistent with manufacturer's instructions to maintain a moist, clean wound area.

HOW SUPPLIED

| Product Codes | Size | Quantity |
|---------------|-------------|--------------|
| CM-720.001 | 1.6 g (2mL) | 1 vial/pouch |
| CM-720.010 | 1.6 g (2mL) | 10 vials/box |

STORAGE

Store at room temperature (77°F/25°C). Keep away from sunlight. See product pouch for expiration date.

SYMBOLS USED IN LABELING

| ISO 15223-1: 2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements | | |
|---|-------|----------------------------------|
| | 5.1.6 | Catalogue Number |
| | 5.1.5 | Batch Code |
| | 5.4.2 | Do not re-use |
| | 5.2.6 | Do not re-sterilize |
| | 5.2.8 | Do not use if package is damaged |
| | 5.1.4 | Use-by date |
| | 5.2.4 | Sterilized using irradiation |
| | 5.4.3 | Consult instructions for use |
| | 5.3.2 | Keep away from sunlight |
| | 5.4.4 | Caution |
| | 5.1.1 | Manufacturer |
| | 5.3.6 | Upper limit of temperature |

For product ordering information, further information, or guidance, please contact Omeza for assistance at: 1-888-88OMEZA (1-888-886-6392)

PRODUCT INFORMATION DISCLOSURE

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Omeza LLC
25 S Osprey Avenue
Sarasota, FL 34236

www.omezapro.com

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