OMEZA®

OCM™

℞ Only

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

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

OCM™ is a wound care matrix comprised of hydrolyzed fish peptides 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. OCM™ 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.

OCM™ is supplied in a sterile single use inner package.

INDICATIONS FOR USE

OCM™ 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.

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 OCM™ is for single use. Discard all opened and unused portions after each treatment session.
- Contents are sterile if the inner package is unopened and undamaged. Do not use if the inner package 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 OCM™ 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 OCM™ devices in one day
- Do not apply more than 4 OCM™ devices in one week

Initial application

1. Always handle OCM™ using aseptic techniques. Only inner package content is sterile.
2. Prior to application of OCM™, 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. Remove the tip of the OCM™ package.
4. Slowly squeeze 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).
5. After application, cover with an appropriate dressing to maintain OCM™ adherence and protect the wound area. The optimum dressing is determined by wound location, size, depth, and volume of exudate.

(OVER)

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 OCM™ 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 OCM™ 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	1 device/pouch

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		
REF	5.1.6	Catalogue Number
LOT	5.1.5	Batch Code
	5.4.2	Do not re-use
	5.2.6	Do not resterilize
	5.2.8	Do not use if package is damaged
	5.1.4	Use-by date
STERILE R	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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