KeraStat® Cream
Wound Dressing **Rx Only**

Manufactured For: KeraNetics Inc., Winston-Salem, NC 27101 USA

PRODUCT DESCRIPTION

KeraStat® Cream is a non-sterile, non-implantable wound dressing intended to provide a moist environment in the management of a variety of partial thickness dermal wounds. KeraStat® Cream is provided in a screw top tube. Each tube contains keratin protein incorporated into a cream base.

KeraStat® Cream is intended to maintain a moist wound environment. KeraStat® Cream is indicated for the management of a number of partial thickness skin wounds such as: partial thickness (first and second degree) burns, severe sunburns, superficial injuries, cuts, abrasions, and incisions/ surgical wounds. Under the direction of a healthcare professional, KeraStat Cream also may be used in the management of dry, light, and moderately exuding partial thickness wounds including: pressure (stage I-II) ulcers, venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, radiation dermatitis, donor sites, and grafts. KeraStat® Cream is not indicated for full thickness or third degree burns. This device will be available by prescription.

CONTRAINDICATIONS

KeraStat® Cream is not indicated for full thickness or third degree burns.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

WARNINGS / PRECAUTIONS

The device should not be used on skin undergoing immunohistochemical testing for skin cancer. In vitro analyses determined that an immune reagent used to detect Merkel cell carcinoma weakly reacts with the keratin in KeraStat® Cream.

KeraStat® Cream should not be used on bleeding wounds until the bleeding has been stopped.

Caution is advised on infected wounds.

KeraStat® Cream should not be used on skin rashes related to food or medicine allergies or when an allergy to one of the ingredients is known.

KeraStat® Cream should be applied at a frequency recommended by the physician.

Contact a health care professional if (1) signs of infection occur (e.g., increased pain), (2) there is a change in wound color and/or odor, (3) the wound does not begin to show signs of healing, or (4) any other unexpected symptoms occur.

KeraStat® is for external use only and should not be ingested. It should not be used for ophthalmic use.

KeraStat® Cream should not be used on more than 10% of the total body surface area (TBSA) for children under 18 years.

In radiation therapy, KeraStat® Cream may be applied as directed by the treating physician. Do not apply 4 hours prior to a radiation session.

KeraStat® Cream may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

Keep this and all similar products out of reach of children.

DIRECTIONS FOR USE

Partial Thickness Wounds:

1. Prepare wound area to ensure wound is free of debris and/or necrotic tissue. The wound may be debrided to ensure the wound edges contain viable tissue if determined clinically necessary.
2. Inspect the KeraStat® Cream tube to ensure that it has not been damaged or is past its expiration date. For first use, ensure that the tube has not been opened and puncture the internal seal on the KeraStat® Cream tube using the cap.
3. Apply KeraStat® Cream directly to the injured site and spread to form a thin layer over the wound surface and edges of normal adjoining skin. Ensure the entire wound surface is covered with the cream.
4. A secondary dressing may be applied if desired.
5. If cream remains in the tube, recap and store.

Radiation Dermatitis:

1. Apply a generous amount of KeraStat® Cream twice a day, seven days a week to the treated area(s), gently massaging the area(s) until KeraStat® Cream is completely absorbed.
2. KeraStat® Cream may be applied as indicated by the treating physician (see Warnings).
3. Continue to apply KeraStat® Cream as described above until the skin has fully recovered.
4. Do not interrupt applications during the course of radiation therapy, even for one day.
5. Do not apply KeraStat® Cream 4 hours prior to a radiation session.

RECOMMENDED CARE

The dressing may be changed every 1 to 3 days, or as directed by a healthcare practitioner. When changing the dressing, gently flush the wound bed with a gentle cleanser as determined by the healthcare practitioner and then apply KeraStat® Cream by fully covering the wound and applying a secondary occlusive dressing, if needed.

KeraStat® Cream can be reapplied every 1 to 3 days for up to 30 days. If wound healing does not improve within 30 days, consult a healthcare practitioner.

PACKAGE CONTENT

Each package contains one tube of KeraStat® Cream.

INGREDIENTS

Purified water, glycerin, mineral oil, keratin, caprylic triglyceride, dimethicone, sodium polyacrylate, hydrogenated polydecene, trideceth-6, sodium stearoyl glutamate, phenoxyethanol, and ethylhexylglycerin.

STORAGE

KeraStat® Cream should be stored in dry conditions at 59-86°F (15-30°C).
Do not use contents of KeraStat® Cream if the tube appears damaged or is past expiration date.

KeraStat®is a registered trademark, and the product incorporates patented and/or patent pending technologies owned by KeraNetics Inc.

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