

PRODUCT DESCRIPTION:

KOTSZR® CMC is a soft, sterile, single-use, conformable, non-woven dressing used for the management of wounds with moderate to heavy exudate, to absorb and retain wound fluid, forming a gel when wound exudate comes in contact with the dressing. The high exudate absorption capacity promotes wound healing.

COMPOSITION:

KOTSZR® CMC dressing is made from Carboxymethyl cellulose and Strengthening cellulose fibres. It is conformable, non-woven dressing with a white/off-white colour made of 100% Carboxymethyl cellulose fibres.

ACTION:

KOTSZR® CMC helps to create an ideal environment for wound healing by absorbing wound exud. The dressing forms a gel when in contact with wound exduate and cellulose fibre ensures that the integrity of the dressing is retained and assists in maintaining a moist wound environment, supporting autolytic debridement and thus supporting the healing process. Debris absorbed in the wound exudate and retained within the dressing is removed when the dressing is changed.

INDICATIONS:

KOTSZR*CMC can be used for the following wounds under the supervision of medical professionals-

- Used for the treatment of Leg Ulcers, Pressure Ulcers and Diabetic Ulcers.
- Used for Surgical Wounds (e.g. Post-operative, wounds left to heal by secondary intent).
- · Used for Partial Thickness Burns.
- Used for Traumatic Wounds (e.g. abrasions and lacerations).
- $\boldsymbol{\cdot}$ The product can also be used under compression.

If required, the dressing can be used in conjunction with a suitable moisture-retaining secondary dressing to keep the product in place and/or under compression.

WARNINGS:

KOTSZR®CMC is not recommended for use to control heavy bleeding. Do not use on patients with known hypersensitivity to wound dressings. Do not use on dry wounds. Do not use if package is open or damaged. Do not re-sterilize. The product is recommended for single-use only. Functionality is not guaranteed and and there is risk of contamination if reused.

PRECAUTIONS:

- Notify physician if any of the following occurs-
- Irritation (Redness, Inflammation)
- Maceration (Whitening of Skin)
- Hyper-granulation (Excess tissue formation)
- Sterlization method: VD max 25
 Dose Range: 25 ± 2 KGy
- The product is for prescription use only.
- The product is for single use only.
- Wounds must be assessed and managed appropriately, as indicated, under the supervision of a medical professional.
- If signs of infection are detected clinically, the healthcare professional responsible for the treatment must decide on the next course of action.
- No data is available concerning compatibility with topical preparations.
- If signs of an allergic reaction are detected, discontinue the use of the product and seek advice from a healthcare professional on the next course of action.
- KOTSZR®CMC is not intended to be used on wounds with severe bleeding,inside internal body cavities or closed wounds.
- · For external use only.

GUIDELINES FOR USING KOTSZR®CMC DRESSING:

SITE PREPARATION:



Debride when necessary and irrigate/clean the wound site in accordance with the standard protocol.

DRESSING SELECTION:

For flat or shallow wounds, select an appropriate size dressing that allows for a minimum of 0.5 cm overlap onto the skin surrounding the wound (to allow for the dressing to gel and to maximize conformability). Use a ribbon (Rope form) dressing for cavity wounds.

DRESSING APPLICATION:



- 1. Always use aseptic techniques when dressing a wound.
- Take out the dressing from the pouch and cut, fold or layer it to fit the wound (loosely fill deep wounds), to allow KOTSZR®CMC to absorb wound fluid and to expand, filling the wound
- 3. Caution: Do not pack tightly.
- When using KOTSZR®CMC ribbon dressing in deep cavity wounds, insert the ribbon in one piece and leave at least 2.5cm outside the wound for ease of removal.
- 5. Cover and secure with an appropriate secondary dressing.
- For dry wounds (to aid a moist wound environment), place KOTSZR®CMC on the wound and moisten with sterile water or saline over the wound area only.
- Cover the dressing with an occlusive or semi-occlusive dressing to maintain moisture at the wound site and to avoid subsequent dressing adherence to the wound.

DRESSING CHANGE AND REMOVAL:



If simple removal of the dressing is difficult due to adherence, saturate the dressing with sterile saline or sterile water to fully hydrate the dressing and remove it gently.

FREQUENCY OF CHANGE:

KOTSZR CMC dressing change will depend on the type and condition of the wound. Generally should be changed daily in heavily exuding wounds or infected wounds, reducing to twice weekly changes as healing proceeds. Change the dressing if wound exduate begins to pool within the wound or if the secondary dressing becomes saturated with exduate. When used on infected wounds, the infection should be inspected and treated in accordance with local clinical protocol. For best results, change KOTSZR CMC before it reaches the maximum absorption capacity. For heavily exuding wounds, dressing change on every alternate day is recommended.

Irrigate the wound site with a suitable wound cleanser (e.g. sterile saline) prior to application of a new dressing.

STERIE F	Sterilied using irradiation.	* Keep away from sunlight.
	Temperature limit.	Consult instructions for use.
Ø	Do not use if package is damaged.	Caution.
②	Do not re-sterilize.	LOT LOT number.
2	Do not re-use.	Date of manufacture.
-	Keep dry.	Expiry date.

HOW SUPPLIED:

KOTSZR CMC is supplied in the following sizes-

PRODUCT CODE	SIZE
KZCMC0510	5×10 cm
KZCMC1010 KZCMC1515	10×10 cm 15×15 cm
KZCMC1020	10×20 cm
KZCMC1520	15×20 cm
KZCMC0230	2×30 cm
KZCMC3060	30×60 cm

STORAGE:

Store in a cool & dry place. Avoid direct sunlight, heat and moisture. The use by date of this product is printed on the packaging.



Manufactured By:

Anziam Bio Pvt. Ltd.

E-127B, Near Vande Mataram Chowk, RIICO Industrial area, Bhiwadi, District- Alwar, Rajasthan 301019