

Antimicrobial Calcium Alginate Dressing with Strengthening Fibre and Silver

PRODUCT DESCRIPTION:

KOTSZR®CA+Ag is a soft, sterile, single-use, conformable, non-woven dressing used for the management of wounds with moderate to heavy exudate. It is designed to absorb and retain wound fluid, together with any bacteria and wound debris that may be present in the fluid, while maintaining its structure intact and forming a gel when wound exudate comes in contact with the dressing.

COMPOSITION:

KOTSZR®CA+Ag is a soft, conformable, non-woven dressing with a beige to light brown color made of a fabric blend between calcium alginate fibres and silver alginate fibres, and strengthening cellulose fibres, providing a strengthened fabric dressing with gelling fibres, which retain the wound exudate.

ACTIONS:

KOTSZR®CA+Ag helps to create an ideal environment for wound healing by absorbing wound exudate. The absorption of exudate assists in maintaining a moist wound environment, supporting autolytic debridement and thus supporting the healing process. Debris and any bacteria absorbed in the wound exudate and retained within the dressing are removed when the dressing is changed. The silver ions released into the dressing impart an antimicrobial action when wound exudate encounters the dressing. KOTSZR®CA+Ag can be used for the treatment of wounds at risk of infection and infected wounds. The high vertical absorption of exudate into the fibre dressing protects the wound environment and the wound edge, thus supporting the healing process.

INDICATIONS:

KOTSZR®CA+Ag can be used for the treatment of wounds at risk of infection and infected wounds under the supervision of medical professionals which are-

- Used for Pressure ulcers (Stage II to IV).
- Used for Arterial ulcers.
- Used for Venous lower leg ulcers.
- Used for Diabetic ulcers.
- Used for Post-operative wounds.
- Used for Skin grafts and Donor sites.
- Used for Wounds with Moderate to Heavy Exudate of any etiology.
- Used for the treatment of Acute or Chronic Wounds.
- 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).
- Used for Exuding Oncology Wounds.
- Used for Cavity Wounds.
- 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®CA+Ag is not recommended to be used to control heavy bleeding. Do not use it on patients with known hypersensitivity to wound dressings. Do not use it on dry wounds. Do not use it if the package is open or damaged. Do not re-sterilize. The product is recommended for single-use only. Functionality is not guaranteed and 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)
- Sterilization method: VD_{max}25
 Dose Range: 25 ± 2 KGy
- KOTSZR CA+Ag wound dressing/packing rope must be used under medical supervision.
- Wounds must be assessed and managed appropriately, as indicated under the supervision of a medical professional.
- 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.
- 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.
- Avoid contact with electrodes or conductive gels during electronic measurements (e.g. EEG or ECG).
- Do not use it on patients undergoing magnetic resonance imaging (MRI).
- Application in the case of heavily bleeding wounds, during pregnancy or lactation is decided on by the treating physician. At present, no documented clinical experience with the product in such cases are available.
- For use on adult patients only.
- For external use only.

GUIDELINES FOR USING KOTSZR CA+Ag DRESSING:

SITE PREPARATION:

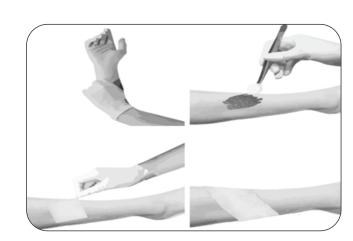


Debride when necessary and irrigate/clean the wound site as per the standard protocol.

DRESSING SELECTION:

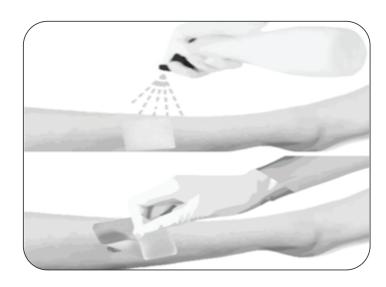
For flat or shallow wounds select an appropriate size dressing that allows for a minimum of 0.5 cm overlap onto the skin surrounding the wound (to allow for the dressing to gel and to maximize conformability). Use a ribbon (Rope form) dressing for cavity wounds.

DRESSING APPLICATION:



- 1. Always use aseptic techniques when dressing a wound.
- **2.** Take out the dressing from the pouch and cut, fold or layer it to fit the wound (loosely fill deep wounds), to allow **KOTSZR®CA+Ag** to absorb wound fluid and to expand, filling the wound.
- 3. Caution: Do not pack tightly.
- **4.** When using **KOTSZR[®]CA+Ag** 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.
- **6.** For dry wounds (to aid a moist wound environment), place **KOTSZR®CA+Ag** on the wound and moisten with sterile water or saline over the wound area only.
- 7. 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®CA+Ag dressing change will depend on the type and condition of the wound. Generally should be changed daily in heavily exuding wounds or infected wounds, reduced to twice weekly changes as healing proceeds. Change the dressing if the wound exudate begins to pool within the wound or if the secondary dressing becomes saturated with exudate. When used on infected wounds, the infection should be inspected and treated under the local clinical protocol. For best results, change KOTSZR®CA+Ag before it reaches the maximum absorption capacity. For heavily exuding wounds, a dressing change on the alternate day is recommended.

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

STERILE R	Sterilized using irradiation.	誉	Keep away from sunlight.
25 C	Temperature limit.	i	Consult instructions for use.
	Do not use if package is damaged.	<u></u>	Caution.
SYERLIZE STERLIZE	Do not re-sterilize.	LOT	LOT number.
2	Do not re-use.		Date of manufacture.
	Keep dry.		Expiry date

HOW SUPPLIED:

KOTSZR®CA+Ag is supplied in the following sizes-

PRODUCT CODE	SIZE
KZCAAG0510	5×10 cm
KZCAAG1010	10×10 cm
KZCAAG1515	15×15 cm
KZCAAG1020	10×20 cm
KZCAAG1520	15×20 cm
KZCAAG0230	2×30 cm
KZCAAG3060	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

Web: www.anziam.com

Email: care@anziam.com

Tel: +91- 798205562