

## PRODUCT DESCRIPTION:

The ALTRAZEAL Transforming Powder Dressing is a sterile dressing suitable for the covering and protection of exuding wounds such as burns, abrasions, skin graft donor sites, surgical wounds, and chronic, slow-healing wounds. The product consists of a sterile white powder in a single use, sterile foil-laminate pouch. The product is applied to an exuding wound by sprinkling the powder on the open wound. The particles then hydrate and aggregate to a final moisture content of approximately 65% by mass. The aggregated powder becomes a moist, flexible film over the surface of the open wound that provides an ideal moist wound environment supporting cellular function and tissue repair.

ALTRAZEAL is available in either 2-gram or 5-gram pouches. Each gram of the lyophilized powder consists of 84.8% poly-2-hydroxyethylmethacrylate (pHEMA), 14.9% poly-2-hydroxypropylmethacrylate (pHPMA), and 0.3% sodium deoxycholate.

## INDICATIONS:

**For over-the-counter use, ALTRAZEAL may be used for:**

- Abrasions and lacerations

**Under the supervision of a health care professional ALTRAZEAL may be used for:**

- Exuding superficial acute wounds such as skin graft donor sites and second-degree burns (partial thickness burns with exudates, maximum 10% of body surface area)
- Surgical wounds, such as post-operative wounds or dermatological excisions (only as a primary dressing over wound, not to be used as replacement for sutures)
- Chronic, slow-healing wounds such as leg ulcers, pressure ulcers, and diabetic ulcers

ALTRAZEAL dressing should be used under the supervision of a health care professional.

**CONTRAINDICATIONS:** ALTRAZEAL is contraindicated in patients with known sensitivity or allergic reaction to the dressing or its components. ALTRAZEAL is also contraindicated for wounds with no exudate, such as third-degree burns.

## PRECAUTIONS:

### General

- Wear sterile gloves to apply ALTRAZEAL dressing.
- ALTRAZEAL dressing should only be applied to a clean, moist wound surface. Apply sterile normal saline or equivalent to moisten the wound surface before application if required.
- Do not use solutions other than sterile normal saline or equivalent to induce aggregation of dressing.
- This wound dressing should not be applied with oil-based products on the wound surface, particularly ointments, salves, or other treatments. These oil-based products will prevent proper hydration and aggregation at the wound surface.

- The dressing can be used on wounds with infection only under medical supervision with appropriate therapy and frequent monitoring.
- The dressing should be removed, ie with forceps or similar instruments following thorough saturation with sterile normal saline or equivalent.
- In second-degree burns, if the site has not healed within 14 days, consider alternate surgical procedures.
- The management of difficult-to-heal dermal ulcers should be performed by a trained health professional and include appropriate antimicrobial therapy for infection, adequate nutritional support (eg control of blood glucose for diabetic foot ulcers), additional supportive measures (eg use of graduated compression bandaging for venous leg ulcers or pressure relief measures for pressure ulcers), or other care that is determined clinically necessary.

### Risk of Aspiration

Since ALTRAZEAL is a powder, should there be a concern to avoid nuisance dust, health care professionals with respiratory problems or asthma should wear a dust mask approved under appropriate government standards such as type N95 (US) or type P1 (EN143) to avoid inhalation of particles.

## DIRECTIONS FOR USE:

### Information for Health Care Professionals:

- Clean the wound area. Ensure that the wound area is moist. Apply additional sterile saline solution or equivalent if required.
- Ensure no oil-based products are on wound surface.
- Tear open the pouch and pour powder over entire moist wound surface in a thin uniform layer. Amount applied depends on wound depth, size, and amount of exudate.
- Powder can be smoothed with sterile glove or instrument to form a uniform covering that fills and seals the entire wound surface.
- Allow powder to aggregate on wound surface with adsorption of wound exudate.
- If a uniform moist wound dressing has not formed within the first few minutes after application of the ALTRAZEAL, preferably use a spray bottle to mist sterile normal saline or equivalent over the surface of the ALTRAZEAL to speed transformation of the powder into the conforming dressing. Hold the sprayer 6 inches from the surface of the powder. Gently mist the surface and allow droplets of saline to settle onto the powder causing aggregation. The powder may still appear white and granular, however, the intact dressing will form gradually once a cohesive structure has formed.
- More powder can be applied to areas of the wound with insufficient coverage.
- All wounds should be inspected regularly. Remove the dressing if determined clinically necessary (eg infection, inflammation, excessive bleeding, excessive fluid, irritation).

- ALTRAZEAL can remain in place up to 30 days as long as the wound produces exudate. However, the dressing should be changed if clinically necessary. ALTRAZEAL will remain in intimate contact with the wound surface until the skin underneath heals. Areas of dressing covering intact skin will detach from the remaining dressing and flake off as particles similar to a scab.
- ALTRAZEAL dressing does not require a secondary dressing unless determined to be necessary by a health care professional. If a secondary dressing is required a non-adhesive, vapor-permeable dressing is preferred. Petroleum-based dressings and occlusive or surface contact adhesives should be avoided.
- Care should be taken during showering to prevent saturation of the dressing. Do not submerge the dressing in water.
- Dressing can be removed by saturating with sterile saline for 3-5 minutes, then gently lifting away.
- Keep out of the reach of children below age 12.
- Do not autoclave.

### Information for Patients:

- Do not scratch, pick at, or attempt to lift the dressing from the wound. This will allow germs to enter the area and could possibly cause infection.
- The skin under the dressing and around the dressing may itch and feel dry. You can keep the surrounding skin moist with lotion or recommended products. Try not to allow the products to come into direct contact with the dressing.
- Care should be taken when showering with the dressing in place. Do not submerge the dressing in water.
- Notify a health care professional if the dressing falls off before the wound is healed, or if there are any signs of irritation, sensitivity, allergic reaction, or infection.

**How Supplied:** ALTRAZEAL Transforming Powder Dressing is supplied in foil laminate pouches of 2 grams covering approximately 6 inches x 6 inches area (15 cm x 15 cm) or 5 grams covering approximately 10 inches x 10 inches area (25 cm x 25 cm).

- This product is for single use only. Throw away any unused portion of the product after applying to the wound.
- Contents are sterile unless primary foil laminate pouch is damaged.

### Storage:

Store at room temperature.

Visit website: [www.Altrazeal.com](http://www.Altrazeal.com)

For further customer information and support, please call the toll-free ALTRAZEAL customer service line at **1-866-606-ZEAL (9325)**.

For outside the U.S.A. dial: +1-610-530-3193

750-04902



**altrazeal™**

transforming powder dressing  
nanoflex™ technology

Sterile R • Sterile by Irradiation

### Manufacturer:

Uluru Inc., 4452 Beltway Drive, Addison, TX 75001

### Distributor:

Bio Med Sciences, 7584 Morris Court, Allentown, PA 18106

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**Oct 2008**

750-04902