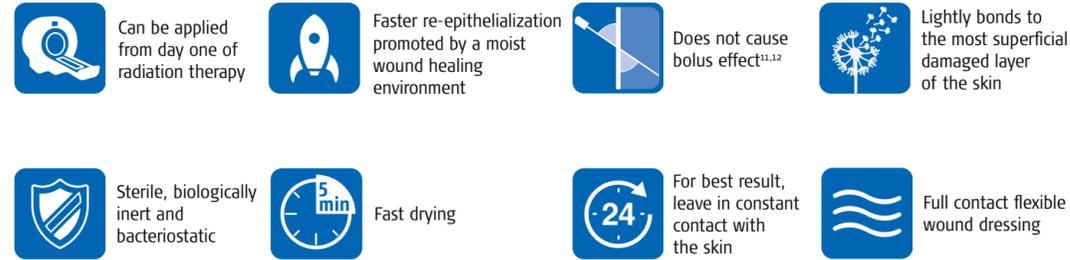


Why is StrataXRT an innovative wound dressing?



Case studies of StrataXRT application

Case study Spain, 2015 Hospital Universitario de Fuenlabrada, Hospital Ruber Internacional, Madrid Spain

A series of case studies was performed on patients with RTOG score of 2.5 ± 0.5 . Patients and nurses reported an overall improvement, reduced itching and pain symptoms. Patients appreciated the ease of use as well as the comfort provided by StrataXRT.¹³



Before StrataXRT treatment

After 72 hours of treatment

After 10 days



Patient showing RTOG 3 radiation dermatitis with moderate edema and a confluent moist desquamation.

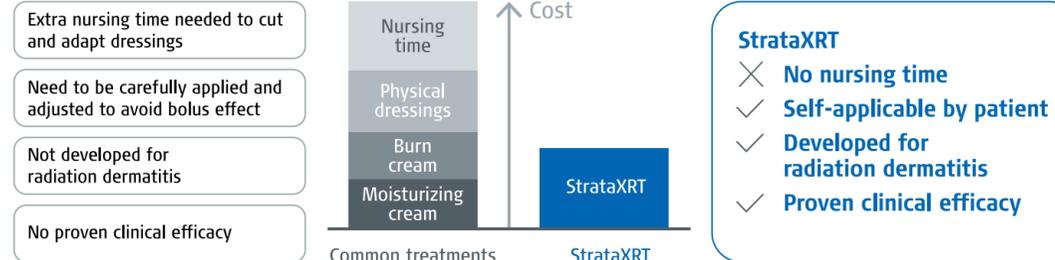


Patient applied StrataXRT during ongoing radiation therapy. After 19 days of topical treatment, a reduction of edema and erythema, and closure of the wound was observed.

StrataXRT vs common treatment regimen

StrataXRT reduces the severity of radiation induced skin reactions, therefore minimizing the probabilities of not complying with the planned radiation therapy.

Skin care overall costs during radiation therapy treatment



How much StrataXRT is required

StrataXRT gel is a unique formulation that requires substantially less product per application than typical moisturizing creams or barrier ointments.

StrataXRT 20 g (0.7 oz): contains enough gel for over 2 weeks of treatment during a standard fractionation plan* applying the gel twice per day.

StrataXRT 50 g (1.75 oz): contains enough gel for over 5 weeks of treatment during a standard fractionation plan* applying the gel twice per day.

* Standard fractionation is considered to be 5 days per week. 2 weeks post radiation are expected for toxicity peak and 2 weeks more for recovery of the skin. The standard therapy time can therefore extend up to 2 weeks.

How to apply StrataXRT



1. Ensure that the affected skin or superficial wound is clean and dry. Gently pat dry as much excess exudate or wound fluid from the area as possible prior to gel application.

2. Apply a very thin layer of StrataXRT directly to the affected area and allow the gel to dry. It will dry in 5 to 6 minutes.

3. If it takes longer to dry you have probably applied too much. Gently remove the excess with a clean tissue or gauze and allow the drying process to continue.

4. Once dry, StrataXRT may be covered by sunscreen, cosmetics and clothing.

Directions for use

- StrataXRT should be applied once or twice daily to the affected areas or as advised by the physician.
- For best results StrataXRT should be maintained in continuous contact with the skin (24 hrs/day).
- StrataXRT may also be used in conjunction with other adjunctive treatments to improve overall results.
- StrataXRT can be used with or without a secondary protective dressing.

Recommended duration of treatment: StrataXRT is recommended to be applied following the initial radiation dose and should continue to be used for a minimum of 60-90 days (24/7) post-radiation therapy, or until no further improvement is seen. For chronic radiation dermatitis, continued use is recommended until no further improvement is seen.

Ingredients: Polydimethylsiloxanes, siloxanes, alkylmethyl silicones

Caution: For external use only. StrataXRT should not be placed in contact with the eyes. StrataXRT should not be applied over topical medications unless advised by your physician. StrataXRT may stain clothing if not completely dry. If staining occurs, dry cleaning should be able to remove it without damaging the fabric. For correct storage please re-close the tube tightly with the cap. Should your radiation dermatitis show signs of infection or failure to heal after 30 days of initial product application, consult your physician. If irritation occurs, discontinue use and consult your physician. Not suitable for highly exudative wounds, tunnelling wounds or 3rd degree burns. Keep out of the reach of children. Do not use after the expiration (EXP) date printed on the tube. The expiration (EXP) date does not change once the tube has been opened. Do not use if the tube is damaged. **STERILE UNTIL OPENED**

www.strataxrt.com

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CE Class IIa Medical Device
FDA Listed / TGA Registered

Manufactured by: Stratpharma AG, Aeschenvorstadt 57, CH-4051 Basel, Switzerland



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StrataXRT®

for the prevention and treatment of radiation dermatitis

A new approach in the prevention and treatment of radiation dermatitis



Stratpharma
Switzerland

Radiation dermatitis – the unwelcome consequence of a life-saving therapy

Radiation dermatitis is an acute skin reaction affecting approximately 95% of patients who receive radiation therapy to the breast, groins or perineum.^{1,2,3} It generally ranges from erythema to dry or even moist desquamation and can be a source of significant pain, discomfort and psychological distress. In particular, moist desquamation poses the risk of infection and can result in treatment breaks which impair patient outcomes.³

Up to 50–60% of patients receiving cancer treatment will undergo radiation therapy at some stage of their illness.^{1,3,4}

The introduction of modern mega-voltage treatment machines with skin-sparing capabilities have improved but not eliminated skin toxicities.⁵



How do the current therapies rate?

Studies assessing lotions, creams, or emulsions (aloe vera, hyaluronic acid, corticosteroids, sucralfate) either showed no benefit in managing radiation dermatitis or provided conflicting evidence.^{6,7,8}

It is essential that any skin damage is minimized by ensuring that interventions are based upon best practice, and supported by evidence-based guidelines.²

Consensus goals of care for skin reactions during radiation therapy^{7,9,10}

| Consensus goals of care for skin reactions during radiation therapy ^{7,9,10} | StrataXRT scores |
|---|---|
| Initial maintenance of skin integrity | ✓ |
| Reduced potential of further exacerbation of skin reactions | ✓ |
| Minimized water loss and optimized skin hydration by means of topical agents | ✓ |
| Promotion of comfort and compliance | ✓ |
| Reduction of pain and pruritus without causing a bolus effect | ✓ |
| Control of bleeding, odor and excessive exudate | ✓ (in combination with secondary dressing) |
| Provides ideal environment for rapid healing and re-epithelialization | ✓ |
| Promotion of moist wound healing environment where skin is broken | ✓ |
| Protection from trauma and friction | ✓ |
| Protection from infection | ✓ |

The RTOG scale for radiation dermatitis

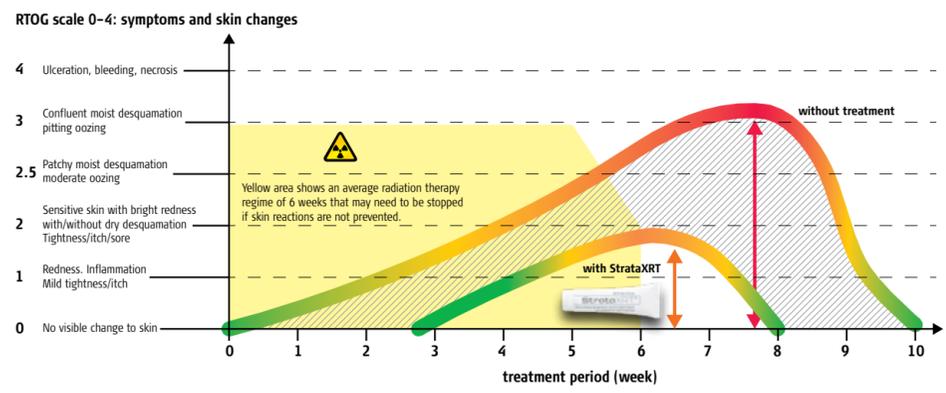
The RTOG scale (Radiation Therapy Oncology Group) provides a standardized description of radiation induced side effects. Interventions are usually matched to the skin's reaction based on its assessment and the RTOG score.

| RTOG Scale Score | Observation: External Signs | Observation: Cellular Level | Clinical Assessment | Treatment Goals |
|------------------|-----------------------------|-----------------------------|--|---|
| 0 | | | No visible change to skin | Maintain soft, supple, clean, odor free and intact skin. |
| 1 | | | Redness. Inflammation Mild tightness/itch | Maintain soft, supple, clean odor free, intact skin, reduce irritation and promote comfort. |
| 2 | | | Sensitive skin with bright redness With/without dry desquamation Tightness/itch/sore | Promote skin hydration, comfort and maintain skin integrity. Reduce itch, pain, soreness and discomfort. |
| 2.5 | | | Patchy moist desquamation Moderate oozing | Reduce risk of complications of further trauma and infection. Reduce pain, soreness and discomfort. |
| 3 | | | Confluent moist desquamation Pitting oozing | Reduce the risk of infection, minimize pain and trauma of the skin. |
| 4 | | | Ulceration, bleeding, necrosis | Debride the wound. Control associated bleeding and oozing (exudate), minimize effects of wound infection. |

Photos from several patients. Other scales of measurement include RISRAS and CTCAE. The key measurement point on this RTOG scale is level 2.5 (2b), which denotes the first level of the appearance of moist desquamation.

Images (RTOG 0–3) courtesy of The Princess Royal Radiotherapy Review Team, St James's Institute of Oncology, The Leeds Teaching Hospitals NHS Trust. Taken from the publication "Managing Radiotherapy Induced Skin Reactions, a Toolkit for Healthcare Professionals".

Progression of symptoms and skin changes according to the RTOG score during radiation therapy*



Area between the curves represents the prophylactic effect of StrataXRT.

* Curve generated from the general progression of radiation dermatitis for patients undergoing radiation therapy. Levels of reaction differ significantly between patients and treatments. If untreated, however, the level of reaction generally follows the shape of this curve.

StrataXRT as prophylaxis

StrataXRT helps to preserve the skin's integrity, by reducing the side effects of ionizing radiation

- StrataXRT creates a protective film that maintains skin integrity and reduces trauma and irritation to the affected site.
 - StrataXRT protects the skin from excessive sloughing of the stratum corneum.
 - StrataXRT helps to prevent the compromised skin from infections.
 - StrataXRT provides a semi-occlusive coverage for optimal hydration of the injured area.
 - StrataXRT reduces the skin's acute inflammatory response.
- StrataXRT does not cause bolus effect.^{11,12}

To be used immediately after the first dose of radiation therapy.

StrataXRT for the treatment of radiation dermatitis

StrataXRT helps to reduce Trans Epidermal Water Loss (TEWL) promoting a moist wound healing environment, leading to:

- Faster re-epithelialization of the skin post therapy.
- Relief of low grade cutaneous changes such as dry, itching, flaking, peeling and irritated skin.
- Reduction of pain, redness and soothing of the exposed skin areas.

