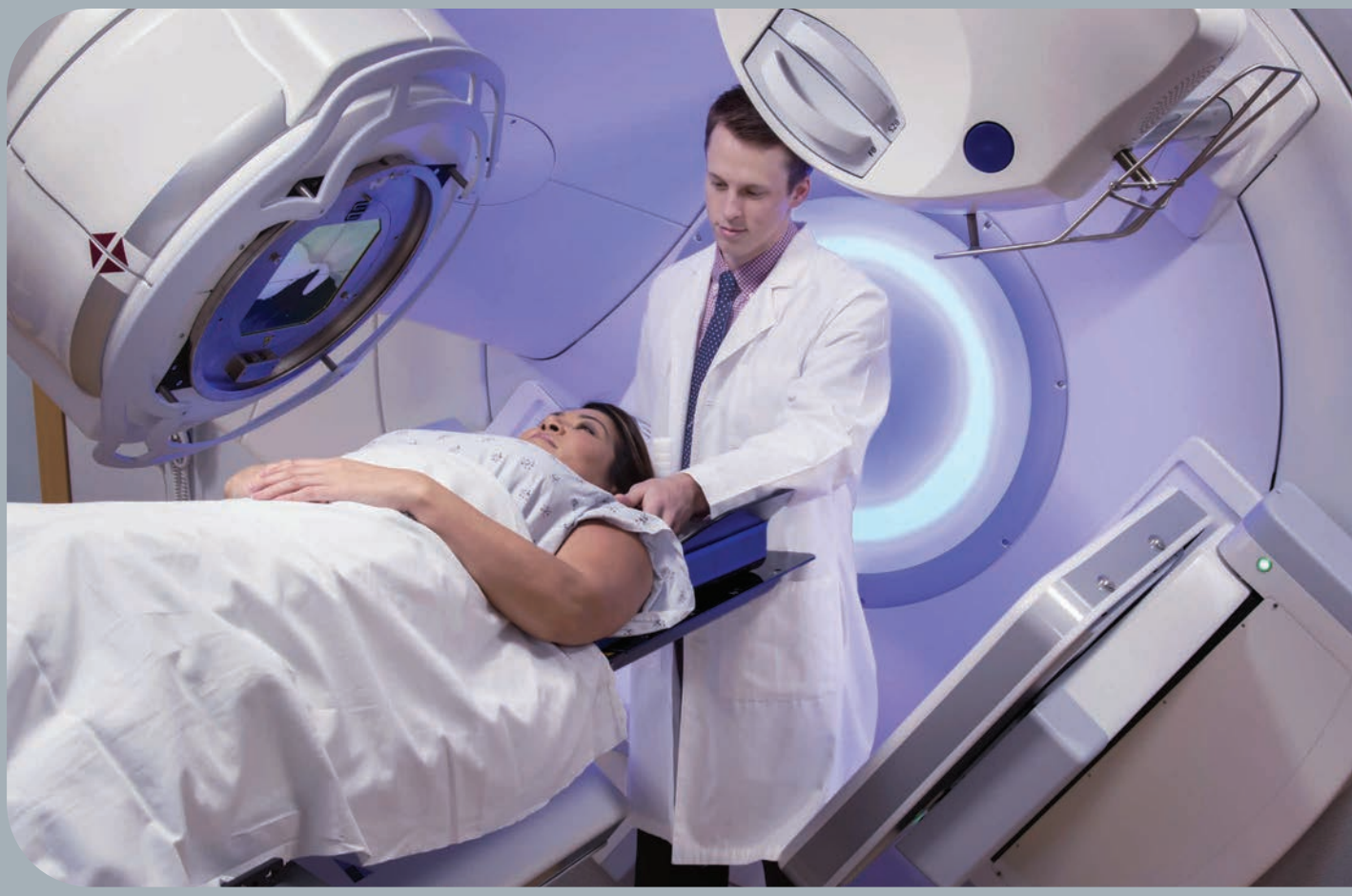
℞ Only
For topical use only
73661-420-50

ADVANCED FORMULATION
Strata xrt®
for the management
of radiation dermatitis

A new approach in the management of radiation dermatitis



Stratpharma
Switzerland

Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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]

Adjuvant **chemotherapy** substantially increases the risk to develop severe skin injuries.[5]
The introduction of modern mega-voltage treatment machines with skin-sparing capabilities have improved but **not eliminated** skin toxicities.[6]

How do current therapies rate?

Systematic reviews on the management of radiation dermatitis found **no evidence** indicating a difference between topical pharmacological treatment and topical non-pharmacological treatment in patients undergoing radiation therapy, except for corticosteroids.[7,8]

Corticosteroids can cause thinning of the skin which can potentially cause skin dehydration.[9]

Studies assessing **lotions, creams and emulsions** (aloe vera, hyaluronic acid, corticosteroids sucralfate, etc.) either showed no benefit in managing radiation dermatitis or provided conflicting evidence.[10-12]

Although there is early evidence suggesting the efficacy of silicone-based film dressings [13,14], these **solid dressings** can have disadvantages like having some small bolus effect.[13,15.]

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]	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 re-epithelialization	✓
Promotion of moist wound healing environment where skin is broken	✓
Protection from trauma and friction	✓
Protection from infection	✓

StrataXRT indicated from the initial radiation dose for the duration of radiation therapy until full skin recovery

StrataXRT is intended to be used under the direction of healthcare practitioners in the management of radiation dermatitis.

StrataXRT is indicated for use on all types of radiation dermatitis, toxic and compromised skin and superficial wounds resulting from radiation therapy. StrataXRT is indicated for the relief of dry, itching, flaking, peeling and irritated skin, as well as the symptomatic relief of pain, redness and heat sensation.

The RTOG scale for radiation dermatitis

RTOG Scale Score	Observation: External Signs	Observation: Cellular Level	Clinical Assessment	Treatment Goals	StrataXRT indicated for use
0			No visible change to skin	Maintain soft, supple, clean, odor free and intact skin.	✓
1			Redness and 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.	✓

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. Photos from several patients. 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".

StrataXRT as prevention[16]

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, reduces friction and irritation to the affected site.
- StrataXRT lightly bonds to the stratum corneum, protecting it from excessive sloughing.
- StrataXRT helps to prevent the compromised skin from infections.
- StrataXRT provides a semi-permeable coverage for optimal hydration of the injured area.
- StrataXRT reduces the skin's acute inflammatory response.
- StrataXRT does not cause bolus effect.[17,18]

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

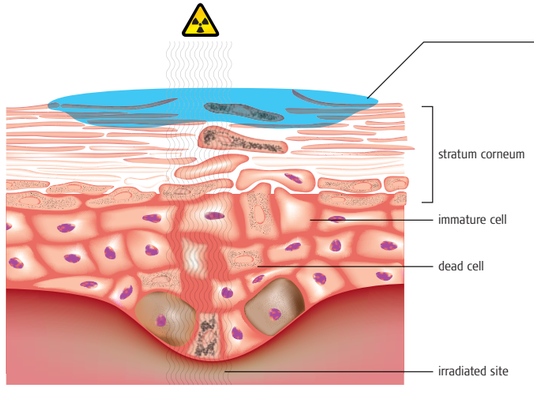
41.0% reduced risk of developing grade 2 skin toxicity.[16]

49.4% reduced risk of developing grade 3 skin toxicity.[16]

StrataXRT for the treatment of radiation dermatitis[19]

StrataXRT reduces 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.



In dry desquamation, StrataXRT protects the fragile epidermis and maintains the skin's integrity, preventing the outmost layers from excessive sloughing.

In moist desquamation, StrataXRT protects the dermal stroma from long term deterioration whilst promoting a moist wound healing environment for the reparative process and reducing the risk of infection.

Why is StrataXRT an innovative product?

FILM-FORMING, FULL CONTACT, FLEXIBLE WOUND DRESSING
StrataXRT dries to form a thin and flexible wound dressing that ensures full constant contact with the skin.

FROM DAY ONE
StrataXRT can be applied from day one of radiation therapy.

NO BOLUS EFFECT
StrataXRT does not cause a bolus effect.[17,18]

FASTER WOUND HEALING
StrataXRT promotes a moist wound healing environment leading to faster re-epithelialization.

SYMPTOMATIC RELIEF
StrataXRT provides symptomatic relief of dry, itching, flaking, peeling and irritated skin, and reduces pain, redness and heat sensation.

HYDRATION
StrataXRT is semi-permeable, which allows the skin to breathe and remain hydrated.

PROTECTION
StrataXRT is bacteriostatic, it protects the skin from irritants and microbial invasion while reducing the risk of contact dermatitis.

NON-REACTIVE
StrataXRT is non-reactive, it has no measurable pH, and contains no alcohol, parabens or fragrances, making it suitable for children, and people with sensitive skin.

FOR DIFFERENT AREAS
StrataXRT is suitable for large surface areas and contoured skin like the breasts, face and neck, back and pelvic area, as well as joints and hairy areas without the need for shaving.

SECONDARY DRESSINGS
StrataXRT can be used in combination with secondary absorbing dressings (in moist desquamation).

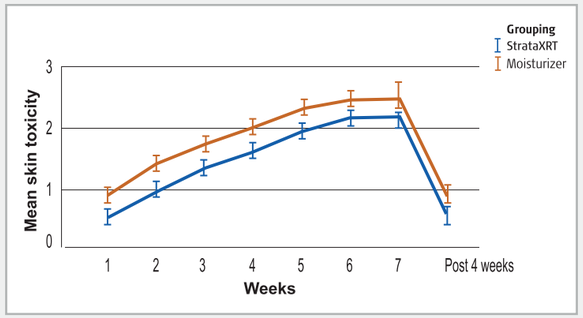
LIGHTLY BONDS
StrataXRT lightly bonds to the most superficial damaged skin layer.

Risk reduction with StrataXRT

A 197-patient study conducted in Australia investigated the effects of StrataXRT versus 10% Glycerine moisturizer (Sorbolene cream) for preventing and managing radiation dermatitis in patients with head and neck cancer receiving radical radiotherapy.[16]

StrataXRT is superior to moisturizer in **preventing and reducing severity** of skin toxicity:

- 41.0% reduced risk of developing grade 2 skin toxicity.
- 49.4% reduced risk of developing grade 3 skin toxicity.
- Lower mean skin toxicity at the end of radiation treatment period.



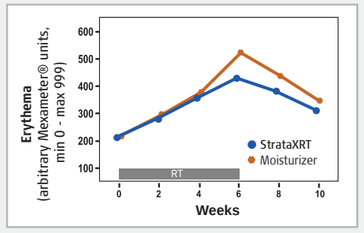
StrataXRT is superior to moisturizer in **delaying severity** of skin toxicity:

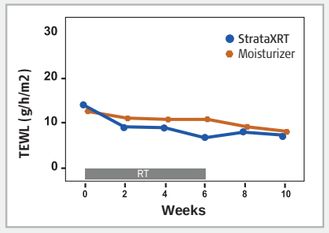
- Longer period without grade 3 skin toxicity with 75% of patients surviving 6 weeks.
- Median of 4 weeks to reach grade 2 toxicity compared to 3 weeks for moisturizer.

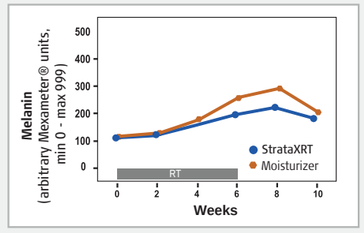
StrataXRT is **easy to apply, acceptable, feasible and effective** for head and neck cancer patients, even in situations where body hair is present.

A 56-patient study was conducted in South Korea where patients who received radiation therapy were randomly assigned to two groups, StrataXRT versus a cosmetic moisturizer cream containing herbal extracts (X-derm).[20]

StrataXRT patients had a significantly lower level of **erythema** (21%) and **Trans-Epidermal Water Loss (TEWL)** (76%)* at 6 weeks and had lower **melanin** changes (31%) at 8 weeks when compared to the moisturizer group.



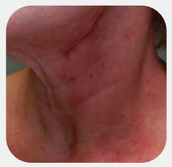




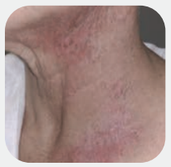
*not statistically significant

A 5-patient case study series was conducted in Spain to explore the use of StrataXRT for the treatment of radiation dermatitis **during concomitant chemotherapy.**[5]

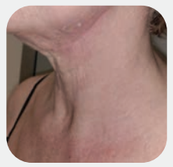
Patients who received StrataXRT were able to **continue the therapy uninterrupted** instead of being at risk of stopping treatment due to the commonly expected deterioration experienced with adjuvant chemotherapy.



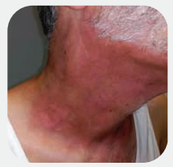
Radiation session 17
Start of treatment
with StrataXRT



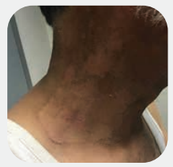
Radiation session 26
After 14 days of treatment
with StrataXRT



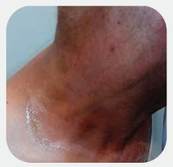
Radiation session 30
After 21 days of treatment
with StrataXRT



Radiation session 21
Start of treatment
with StrataXRT



Radiation session 31
After 10 days of treatment
with StrataXRT



Post-radiation day 4
After 18 days of treatment
with StrataXRT

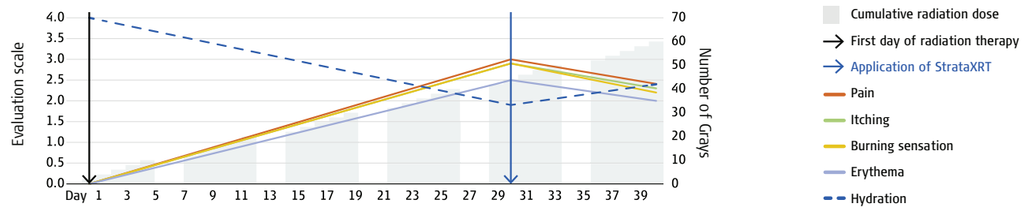
StrataXRT is clinically proven to reduce severity of radiation dermatitis during ongoing radiation therapy

A 54-patient multicenter study performed in Spain focused on the efficacy of StrataXRT as a wound dressing and a monotherapy in the treatment of radiation dermatitis.[19]

Start of StrataXRT therapy: RTOG score of 2.5 ± 0.5 in at least 25% of irradiated area (different cancer types). All patients were treated with StrataXRT **while undergoing radiation therapy (RT).** The common clinical experience is that the radiation dermatitis severity escalates over time and is proportionally associated with the accruing radiation on the tissues.

- After the start of the StrataXRT application, the **improvement** of skin condition, clinical signs and symptoms **during ongoing RT** were observed.
- Use of StrataXRT shows statistically significant evidence of **reducing the severity of radiation dermatitis** during ongoing RT.
- Reduction of radiation dermatitis markers **allows the radiation to be continued,** instead of being interrupted due to an increase of severity of radiation dermatitis.

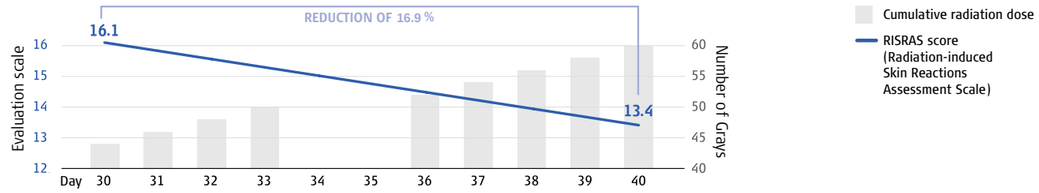
Measurement of clinical signs and symptoms during radiation therapy treatment



During the StrataXRT treatment period, StrataXRT showed:

- decrease of pain by 20.5%
- decrease of itching by 22.2%
- decrease of burning sensation by 24.7%
- decrease of erythema by 20.6%
- improvement of hydration by 26%

Evolution of RISRAS score during radiation therapy treatment and when applying StrataXRT



Although, radiation dermatitis would only worsen during the RT and until approximately 2 weeks after the end of RT, StrataXRT showed clinical improvement:

- Decreasing of RISRAS score by 17% from the beginning of StrataXRT application until the end of RT.
- Decreasing of RISRAS score by 37,6% from the beginning of StrataXRT application until 10 to 14 days after the end of RT.

StrataXRT versus Mepitel Film®

StrataXRT was shown to be **non-inferior to Mepitel Film** on the reported outcome measures of moist desquamation and worst grade of acute radiation dermatitis.[21]

StrataXRT is flexible and allows a **perfect adaptation to body surfaces** in which common physical sheeting are unsuccessful or impossible to use, such as those with high mobility (joints), high friction (axilla), wet skin (mucosa), and higher hygienic necessities (perineum).[5]

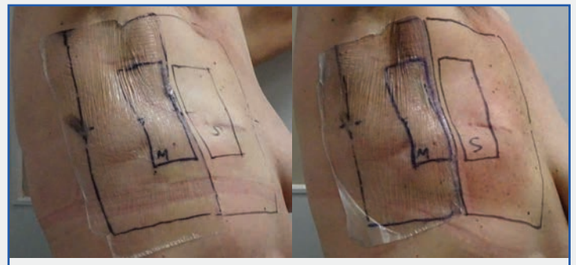
StrataXRT was also found to be **easier to use** and **improved patient adherence** when compared to physical dressings.[22]

StrataXRT is a **more pragmatic choice** as Mepitel Film further extended the utilization of scarce nursing resources.

- The average time per application of Mepitel Film was 15 minutes (range 7.5-50 minutes).
- StrataXRT application does not require any nursing time as it is applied by the patient.[21]

StrataXRT allows the nursing team to **avoid harder to fix**, **more costly** and **more time consuming physical dressings.** Only a small amount of StrataXRT was necessary and adherence by patients was improved as StrataXRT is transparent when applied.[22]

StrataXRT does not need to be removed, which can be traumatic for patients when dressings need to be removed and reapplied.[19]



Patient at commencement of radiation therapy with Mepitel Film of the lateral half of the right chest wall and StrataXRT on the medial half of the right chest wall.

7 weeks after commencement of radiation therapy.[4]

n = 40, randomized Mepitel half, StrataXRT half

Three patients developed itching from Mepitel Film with early removal on one patient.[21]

Effective resource management

StrataXRT is clinically proven to reduce the severity of radiation induced skin reactions improving the **patients quality of life**[6] and minimizing the probabilities of not complying with the planned radiation therapy (StrataXRT **reduces treatment breaks**).

A reduction of patients with radiation-related skin toxicity will:[19]

- Reduce additional resources associated with radiation therapy discontinuation.
- Benefit the radiation unit's planning and use of resources.
- Support better health outcomes.

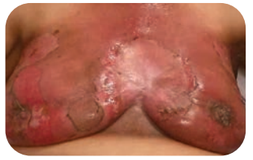
StrataXRT has simplified current dressing protocols which means the **average time** spent with each patient is significantly reduced.[23]

Participants using StrataXRT required **fewer nursing occasions** of service managing radiodermatitis.[24]

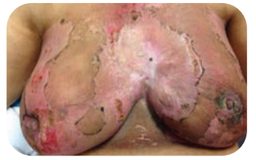
Before and After Cases

A 64 year old female patient with a bilateral carcinoma with cutaneous infiltration with supraclavicular and multiple axillary adenopathy in Spain. Prior to radiation therapy the patient received 4 cycles of Adriamycin and cyclophosphamide + 12 cycles of paclitaxel chemotherapy. StrataXRT was applied on left breast, standard therapy - on the right breast.[25]

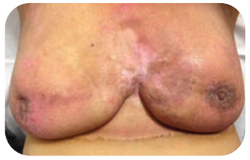
University Hospital - Fuenlabrada, Madrid, Spain



7 days post radiation therapy.
Start of treatment
with StrataXRT



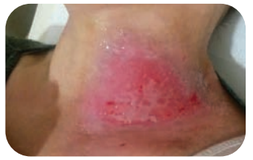
72h post treatment with
standard therapy on the R-Breast
and StrataXRT on the L-Breast



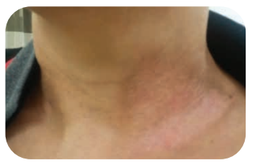
After 10 days of treatment
with StrataXRT

A series of case studies were performed in South Korea to assess the efficacy of StrataXRT on head-and-neck patients.[26]

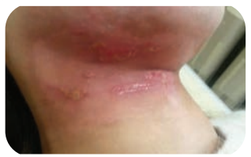
- An overall improvement with reduced itching and pain symptoms was observed.
- StrataXRT promotes a moist wound healing environment for faster re-epithelialization.
- StrataXRT significantly reduces the skin's acute inflammatory response and risk of infection.



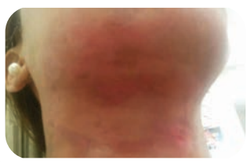
Start of treatment
with StrataXRT



After 7 days of
treatment with
StrataXRT

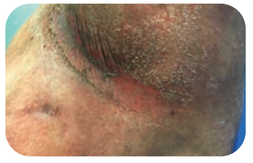


Start of treatment
with StrataXRT

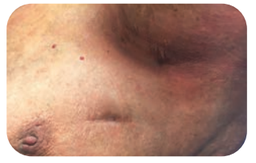


After 3 days of
treatment with
StrataXRT

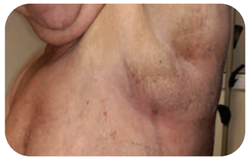
Neoplasm of breast[27] **- Clinica IMQ Zorrozaurre, Bilbao, Spain**



Radiation session 19
Start of treatment
with StrataXRT

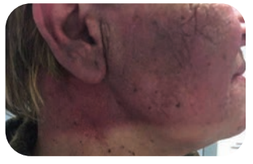


Post radiation day 6
After 7 days of treatment
with StrataXRT

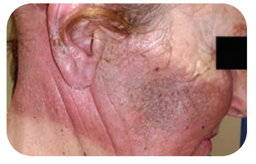


Post radiation day 13
After 14 days of treatment
with StrataXRT

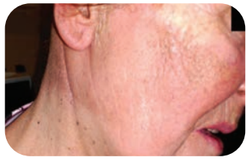
Neoplasm of parotid- Face[27] **- Clinica IMQ Zorrozaurre, Bilbao, Spain**



Radiation session 21
Start of treatment
with StrataXRT



Post radiation day 2
After 13 days of treatment
with StrataXRT



Post radiation day 18
After 29 days of treatment
with StrataXRT

Dosage and Administration

StrataXRT gel is a unique formulation that requires **substantially less product** per application than typical creams or gels.

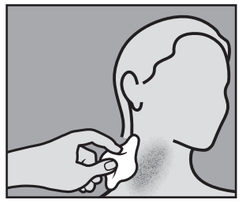
StrataXRT 1.75 oz (50g) is enough to treat an area of 6×12 inch (15×30 cm) twice per day for 30 days.

0.35oz (10g) of StrataXRT is enough for approximately 1 week of application.

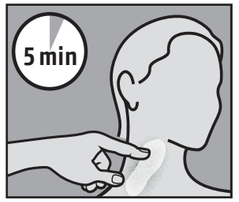
How supplied:

StrataXRT 1.75oz (50g) tube (73661-420-50)

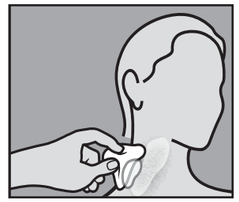
Directions for use



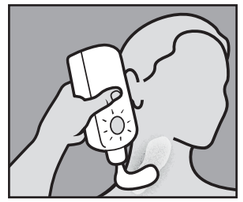
1. Ensure that the affected skin or superficial wound is clean and dry. Gently pat dry as much excess exudate or wound fluid from the area as possible prior to gel application.



2. Apply a **very thin layer** of StrataXRT directly to the affected area and allow the gel to dry. When applied correctly to exposed areas, StrataXRT should be **dry in 5–6 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.

Additional directions

- StrataXRT should be applied **once or twice daily** to the affected areas or as required to maintain contact with the affected surface.
    - StrataXRT may be re-applied **more often** to ensure constant contact with the skin, or to reduce symptoms.
    - Washing will likely remove StrataXRT. Re-apply StrataXRT **after each wash**.
    - Areas with **higher hygienic necessities** (groin, perineum, anal): StrataXRT should be applied after each urination and bowel movement, on dry and clean skin.
    - For best results StrataXRT should be maintained in **continuous contact** with the skin (24 hours a day/7 days a week).
- StrataXRT **does not need to be removed** prior to radiation therapy.
- StrataXRT can be used with or without a secondary protective dressing.
- StrataXRT **does not need to be rubbed in or massaged**, as it does not penetrate below the level of stratum corneum and will not enhance its effect.
- StrataXRT can be applied directly to the skin, using the finger, Q-tip etc.

Tips for StrataXRT usage

- StrataXRT may be stored in the refrigerator prior to application for faster relief of the burning sensation that may occur following radiation therapy.
- If not completely dry, StrataXRT may stain clothing. Normal washing will not remove the product from the clothes. If staining occurs, dry cleaning should be able to remove it without any damaging of the fabric.

StrataXRT and other products

Moisturizers, lotions, burn creams etc. are not required. StrataXRT can be re-applied more often to avoid dry and tight skin feeling, as StrataXRT prevents the water evaporation through the damaged skin that may cause this feeling. Alternatively, a moisturizer can be applied after StrataXRT dries to maintain the first contact of StrataXRT with the skin.

StrataXRT reduces the need for antibiotics.
StrataXRT is bacteriostatic and prevents microbial and bacterial invasion without the risk of contact dermatitis.

StrataXRT reduces the need for corticosteroids.
StrataXRT reduces skin's acute inflammatory response without side effects of corticosteroids.

IMPORTANT

Due to StrataXRT's semi-permeable nature:

- StrataXRT may enhance the effect of an active ingredient if StrataXRT is applied over the active ingredient.
- StrataXRT may prevent or reduce absorption of active ingredients if they are applied over StrataXRT.

Secondary dressing. StrataXRT will not absorb exudate. In moist desquamation, StrataXRT should be used in combination with absorbent dressings. StrataXRT should be the first layer of contact with the skin. StrataXRT does not need to dry before applying the secondary dressing.

Additional prescribing information

Therapeutic group: Wound dressing for the management of radiation dermatitis.

Pharmaceutical form: Occlusive, non-resorbable, self-drying and transparent gel.

Description: When used as directed StrataXRT dries to form a protective layer that is gas permeable and waterproof which hydrates and protects compromised skin areas and superficial wounds from chemical and microbial invasion. StrataXRT helps to promote a moist wound healing environment. This moist wound healing environment promotes faster re-epithelialization* and reduces the skin's acute inflammatory response seen with both dry and moist desquamation.

Warnings: 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 reclose the tube tightly with the cap. If irritation occurs, discontinue use and consult your physician. 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.

Contraindications: Do not administer to patients with known hypersensitivity to the ingredients of this product.

Side effects: At the time of producing this material, no adverse effects have been reported with the use of StrataXRT.

Drug interactions: None known.

Use in specific populations: No specific population restrictions, StrataXRT is suitable for children and people with sensitive skin.

Storage: Store at room temperature, out of direct sunlight.

*Losi P et al. J Mater Sci Mater Med. 2012;23(9):2235-43

ADVANCED FORMULATION
Strata xrt®
for the management
of radiation dermatitis

℞ Only
For topical use only
73661-420-50

StrataXRT - a new approach in the management of radiation dermatitis

StrataXRT:

- Is indicated from the initial radiation dose for the duration of radiation therapy until full skin recovery
- Reduces pain, redness and heat sensation
- Relives dry, itching, flaking, peeling and irritated skin
- Promotes faster healing
- Hydrates and protects all types of radiation dermatitis, toxic and compromised skin
- Reduces the risk of infection
- Is non-reactive, contains no alcohol, parabens or fragrances

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Ingredients: Dimethylpolysiloxane, dihydroxysiloxane and alkylmethylsiloxane. STERILE UNTIL OPENED.

References: 1. Porock, D., Kristjanson, L. (1999). *European Journal of Cancer Care*, 8, pp. 143-153. 2. Kedge, EM. (2009). *Radiography*, 15, pp. 247-257. 3. Naylor, W., Mallett, J. (2001). *European Journal of Oncology Nursing*, 5(4), pp. 221-233. 4. Lopez, E., et al. (2002). *Breast Cancer Research and Treatment*, 73, pp. 127-134. 5. Villandiego, IA. (2018). *Journal of Cancer Therapy*, 9, pp. 1048-1056. 6. Hymes, S., et al. (2006). *J Am Acad Dermatol*, 54(1), pp. 28–46. 7. Ho, AY, et al. (2018). *Int J Radiat Oncol Biol Phys*, 101, pp. 325–33. 8. Ferreira, EB, et al.(2017). *Support Care Cancer*, 25, pp. 1001–11. 9. Barnes, L., et al. (2015). *Drug Saf*, 38, pp. 493–509. 10. Boldeston, A., et al. (2006). *Support Care Cancer*, 14, pp. 802-817. 11. McQuestion, M. (2006). *Seminars in Oncology Nursing*, 22(3), pp. 163-173. 12. Wickline, MM. (2004). *Oncology nursing forum*, 31(2), pp. 237-244. 13. Herst, M., et al. (2014). *Radiother Oncol*, 110, pp. 137–43. 14. Wooding, H., et al. (2018). *Br J Radiol*, 91(1081); doi: 10.1259/bjr.20170298. 15. Diggelmann, KV, et al. (2010). *Br J Radiol*, 83, pp. 971–978. 16. Chan et al., (2019). *Radiotherapy and Oncology*, 139, pp. 72-78. 17. Data on file, 2018 (Dr. J. Ekeberg, University Hospital Basel. Basel, Switzerland). Stratpharma AG. 18. Data on file, 2017 (A. Walsh, ROC. Springfield, Australia). Stratpharma AG. 19. Quilis, A., et al. (2018). *Journal of Radiation Oncology*, 7(3), pp. 255- 264. 20. Ahn, et al. (2020). *In Vivo*, vol. 34 (1), pp. 413–422. 21. Data on file, 2019 (Chao. M. Austin Hospital, University of Melbourne, Australia). Stratpharma AG. 22. Data on file, 2015 (Ribes. JL. Institut Català d'Oncologia Barcelona, Spain). Stratpharma AG. 23. Data on file, 2015 (Rodriguez C. Oncology Institut Group of Madrid (IMO) Madrid, Spain). Stratpharma AG. 24. Data on file, 2019 (Blades. R et al, Brisbane, Australia). Stratpharma AG. 25. Data on file, 2015 (Hospital Universitario de Fuenlabrada, Hospital Ruber Internacional. Madrid, Spain). Stratpharma AG. 26. Data on file, 2015 (Hee-Jung Kim, Seoul, Republic of Korea). Stratpharma AG. 27. Data on file, 2016 (S. Gonzalez Aramberri, I. Arranz Villandiego). Stratpharma AG.

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