

Rx Only
For topical use only
73661-420-50

ADVANCED FORMULATION
Strata xrt[®]
for the management
of radiation dermatitis

A new approach to
support you along the
radiation therapy journey



 **Stratapharma**
Switzerland

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

What is radiation dermatitis?

You and your doctor have decided to start radiation therapy. Radiation therapy uses high doses of radiation to destroy fast growing cancer cells (e.g. to shrink tumors).

The radiation that destroys cancer cells also injures nearby healthy skin cells, like the fast-growing basal layer of your skin. This is why you may experience some side effects on your skin called **radiation dermatitis**.

You will see the skin damage approximately **10–14 days after the first fraction of radiation**, corresponding to the time it takes for the damaged skin cells to migrate to the surface of your skin.¹

If the new cells are produced faster than the old cells are shed, your skin will become **dry and flaky** (dry desquamation).²

As radiotherapy continues, your skin may not produce enough new cells to replace the old ones. Therefore, the outer layer of your skin may become **broken and oozing** (moist desquamation).²

The severity of the skin reactions may increase for **2 weeks after your radiation therapy is completed**, as new skin cells replace the damaged ones.

Radiation dermatitis is **different from burns**;

The damage happens in the deeper layers of your skin.

How radiation therapy affects skin function

Radiotherapy starts

1. No visible changes. However, skin cells are damaged from the first dose of radiation.



2. The inflammatory response is activated in response to this insult. Damaged cells migrate to the skin's surface at an increased rate.



3. The rate of new skin cell production is increased to cope with the radiation damage – dead skin layer becomes thicker and dry.



4. The rate of new cell production is insufficient to replace those lost to radiation, which causes a break-down in the integrity of the skin. This imbalance continues until radiation therapy is stopped.



Radiotherapy ends

5. New healthy skin cells begin to recover. However, the integrity of the skin may continue to deteriorate until the new cells repopulate the area.



Skin heals

6. Skin in the treated area may not recover to the same appearance as before.



Protect and care for your skin

- Make sure your clothing covers the area being treated when you are outside.
- Wear loose-fitting clothes.
- Choose clothes and bed sheets made of soft materials.
- Avoid direct sunlight; sunscreens should be used to offer maximum protection from sunlight.
- Use non-perfumed, mild soap and toiletries.
- Shower or bathe with warm water and not with hot water.
- Gently pat your skin dry after showers or baths.
- Avoid swimming in chlorinated water as it can have a drying effect on the skin.
- Do not rub off the markings your radiation therapist made on your skin; they show where to place the radiation.
- Do not put anything that is very hot or cold on the area getting radiation.
- Use an electric razor if your doctor or nurse says you can shave.
- Do not “wet-shave” or use hair removal products.

Check with your doctor or nurse before you put anything on your skin.

Remember that common skin care products, cosmetics and deodorants can be **contraindicated or unsuitable** for use with radiation dermatitis-related skin changes.

Tell your doctor or nurse if your skin stays wet or if you have sores.

StrataXRT - an innovative product for the management of radiation dermatitis

StrataXRT is a self-drying and transparent gel.

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

StrataXRT may be used on all types of radiation dermatitis, toxic and compromised skin and superficial wounds resulting from radiation therapy.



FILM-FORMING, FLEXIBLE, FULL CONTACT

StrataXRT dries to form a thin and flexible wound dressing that ensures full constant contact with the skin.



PROMOTES MOIST WOUND HEALING ENVIRONMENT

StrataXRT promotes a moist wound healing environment which leads to faster wound healing.



HYDRATION

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



PROTECTION

StrataXRT protects the skin from irritants 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, back and pelvic area, as well as joints and hairy areas without the need for shaving.



EASY TO USE

StrataXRT is convenient and easy to apply.

Clinical evidence

The common clinical experience is that the severity of radiation dermatitis escalates over time and is proportionally associated with the accruing radiation on the skin.

StrataXRT is clinically proven to **prevent radiation dermatitis and reduce its severity**, even during ongoing radiation therapy.^{3,4}

Patients, who used StrataXRT during radiation therapy combined with chemotherapy were able to **continue the therapy** uninterrupted, instead of being at risk of stopping treatment due to the commonly expected worsening of the skin condition.⁵

Head and neck⁵



Radiation session 17
Start of treatment
with StrataXRT



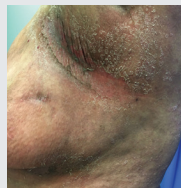
Radiation session 26
After 14 days of
treatment with StrataXRT



Radiation session 30
After 21 days of
treatment with StrataXRT

Clinica IMQ Zorrozaurre, Bilbao, Spain.

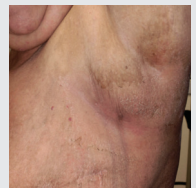
Breast⁶



Radiation session 19
Start of treatment
with StrataXRT



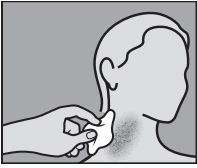
Post-radiation day 6
After 7 days of treatment
with StrataXRT



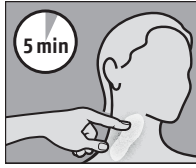
Post-radiation day 13
After 14 days of treatment
with StrataXRT

Clinica IMQ Zorrozaurre, Bilbao, Spain.

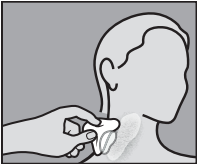
How to apply StrataXRT



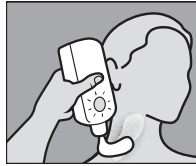
1. Ensure that the affected skin or superficial wound is clean and dry. Gently pat dry as much excess exudate or wound fluid from the area as possible prior to gel application.



2. Apply a **very thin layer** of StrataXRT directly to the affected area and allow the gel to dry. 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**.
- In areas with **higher hygienic necessities** such as the groin, perineum, and anal region, 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 **does not need to be rubbed in or massaged**, as it does not penetrate below the level of stratum corneum, top layer of the skin, 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 damaging the fabric.
- 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.

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 (50 g) tube is enough to treat an area of 6x12 inch (15x30 cm) twice per day for 30 days.

Warnings and Contraindications

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. 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.

StrataXRT - a new approach in the management of radiation dermatitis

StrataXRT:

- Is intended to be used from the initial radiation dose for the duration of radiation therapy until full skin recovery
- Promotes a moist wound healing environment which leads to:
 - Reduction in pain, redness and heat sensation
 - Relief of dry, itching, flaking, peeling and irritated skin
 - Faster healing
- Hydrates and protects all types of radiation dermatitis, toxic and compromised skin
- Is non-reactive, contains no alcohol, parabens or fragrances



Questions about Stratpharma products or prescriptions, contact us at our San Diego Headquarters:

619-930-5788 or customerservice@us.stratpharma.com

Stratpharma Inc, 7676 Hazard Center Drive, Suite 880,
San Diego, CA 92108 USA

us.strataxrt.com

Ingredients: Dimethylpolysiloxane, dihydroxysiloxane and alkylmethylsiloxane. STERILE UNTIL OPENED.
Reference: 1. Porock, D., Kristjanson, L. (1999). *European J of Cancer Care*, 8 (3), pp. 143-153. 2. Kedge, EM. (2009). *Radiography*, 15, pp. 247-257. 3. Chan, et al. (2019). *Radiotherapy and Oncology*, 139, pp. 72-78. 4. Quilis, A., et al. (2018). *Journal of Radiation Oncology*, 7(3), pp. 255-264. 5. Villandiego, IA. (2018). *J of Cancer Therapy*, 9(12), pp. 1048-1056. 6. Data on file, 2016. (S. Gonzalez Aramberri, I. Arranz Villandiego). Stratpharma AG.

Manufactured by: Stratpharma AG Aeschenvorstadt 57 CH-4051, Basel, Switzerland.
Distributed by: Distributed by: Marnel Pharmaceuticals LLC Charleston,
SC 29403, U.S.A. 1-833-788-0312