

Rx Only
For topical use only

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

ADVANCED FORMULATION

StrataXRT®

for the management
of radiation dermatitis

[EN] Description

StrataXRT is an occlusive, non-resorbable, self-drying and transparent gel.

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.

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 and reduces the risk of infection.

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.

Indication for use

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.

StrataXRT may be directly applied to superficial wounds and areas where skin integrity has been compromised.

StrataXRT is bacteriostatic and inert.

StrataXRT contains no alcohols, parabens or fragrances.

StrataXRT can be used with or without a secondary protective dressing.

StrataXRT is suitable for children and people with sensitive skin.

StrataXRT is intended for single patient use.

Directions for use



On the first use of 1.75 oz (50 g) tubes remove the cap, then the protective seal and close with the cap after use.

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.

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. 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.

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

StrataXRT should be applied once or twice daily to affected areas or as advised by your physician.

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.

How much StrataXRT do I need?

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 (15×30cm) twice per day for 30 days.

Warning

- 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.

STERILE UNTIL OPENED

Ingredients: Dimethylpolysiloxane, dihydroxysiloxane and alkylmethylsiloxane.

How supplied:

StrataXRT 1.75 oz (50g) tube

Product identification code

73661-420-50



Consult instructions for use



Use by date



Batch code



Sterilized using irradiation



Do not use if the tube is damaged



Upper limit of temperature

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Aeschenvorstadt 57
CH-4051 Basel
Switzerland

Distributed by
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Charleston, SC 29403, U.S.A.

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*Losi P et al. J Mater Sci Mater Med.
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