

ADVANCED FORMULATION
Strata ctx[®]
Gel for dry skin and cutaneous rashes

A non-steroidal gel for the management of dry skin and cutaneous rashes



Cutaneous reactions - etiology

Cutaneous rashes are inflammatory reactions of the skin, occurring in certain underlying medical conditions, upon administration of medications (systemic or topical) including reactions at an infusion site or reactions to medical adhesives.

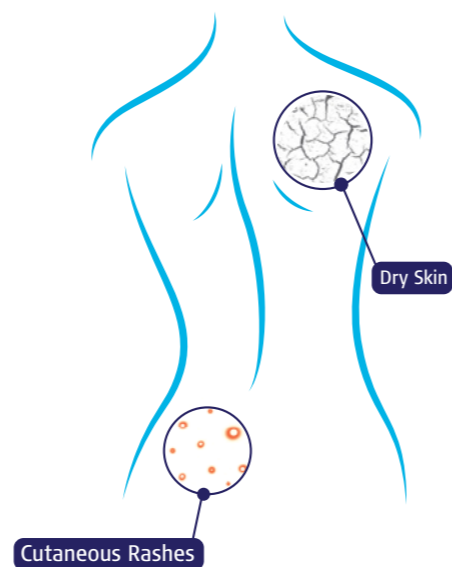
Cutaneous reactions from targeted therapies, such as chemotherapy, immunotherapy or haematological treatments are common and may be predictable.¹

The therapies may cause a wide range of cutaneous reactions, including the damage of the fast growing skin and nail cells. This can lead to problems such as skin that is dry, itchy, red, and/or that peels. Some people may develop a rash or sun sensitivity. Nail changes may include dark, yellow, or cracked nails and/or cuticles that are red and painful.^{1,2}

Cutaneous reactions can have a **negative effect** on a patient's **physical, functional, emotional and social well-being**, and could represent a threat to patient **treatment compliance**.^{1,2}

80% of patients receiving oncology drugs, such as Epidermal Growth Factor Receptor Inhibitors (EGFRI) develop cutaneous reactions of which 10-17% can be severe. Skin reactions may lead to **dose modification and treatment discontinuation** by 36% and 72% respectively thus can **negatively affect the treatment outcome**.³

Early treatment of cutaneous reactions may prevent the exacerbation of symptoms, the need for reducing the medication dose, or the interruption of therapy. It is vital to restore the barrier function of the epidermis, hydrate the affected area, while keeping the skin free from infection or environmental contamination.²



StrataCTX - a breakthrough in management of cutaneous reactions

StrataCTX is a semi-occlusive and self-drying gel.

StrataCTX may be directly applied to dry skin, open wounds and compromised or desquamating skin surfaces, including cutaneous reaction.

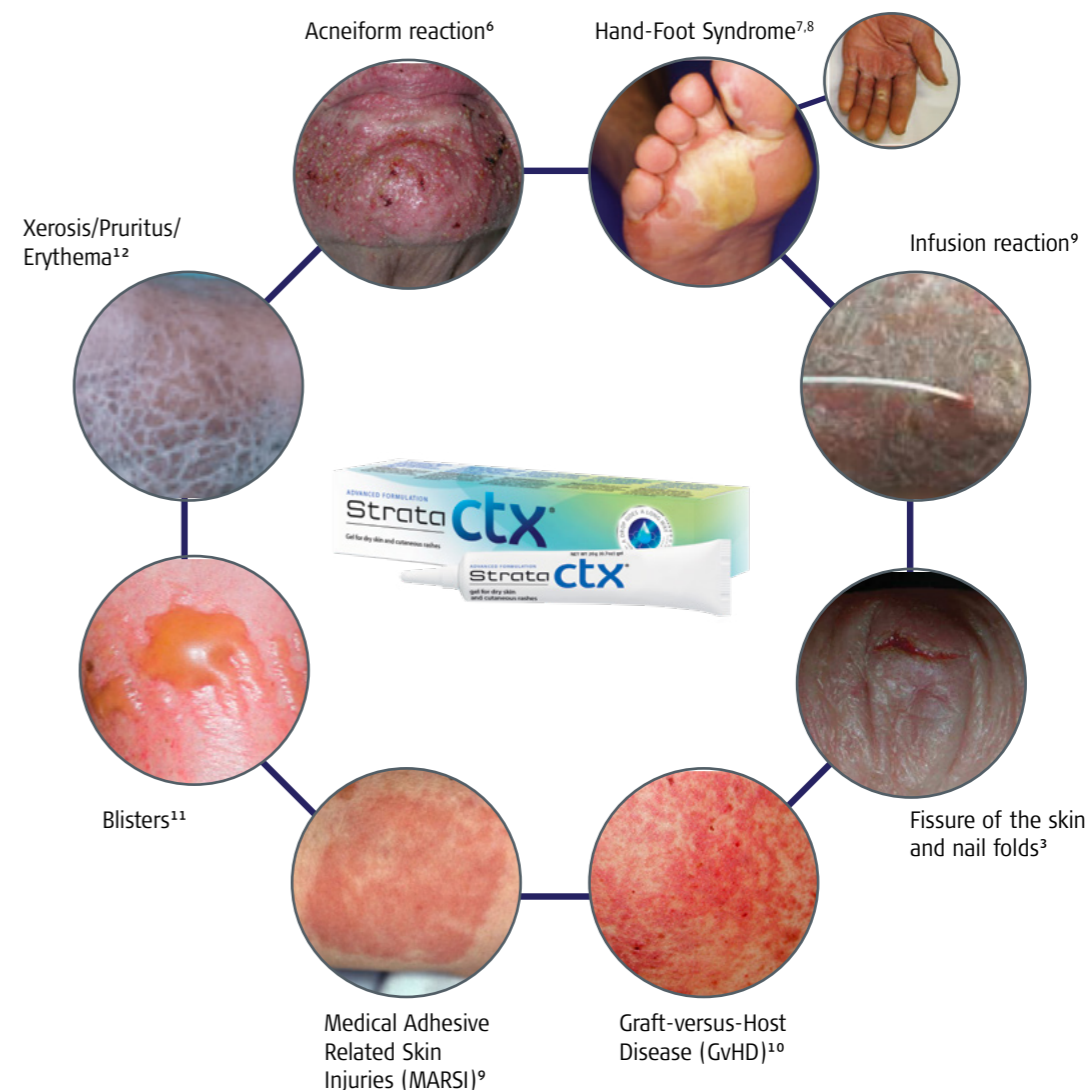
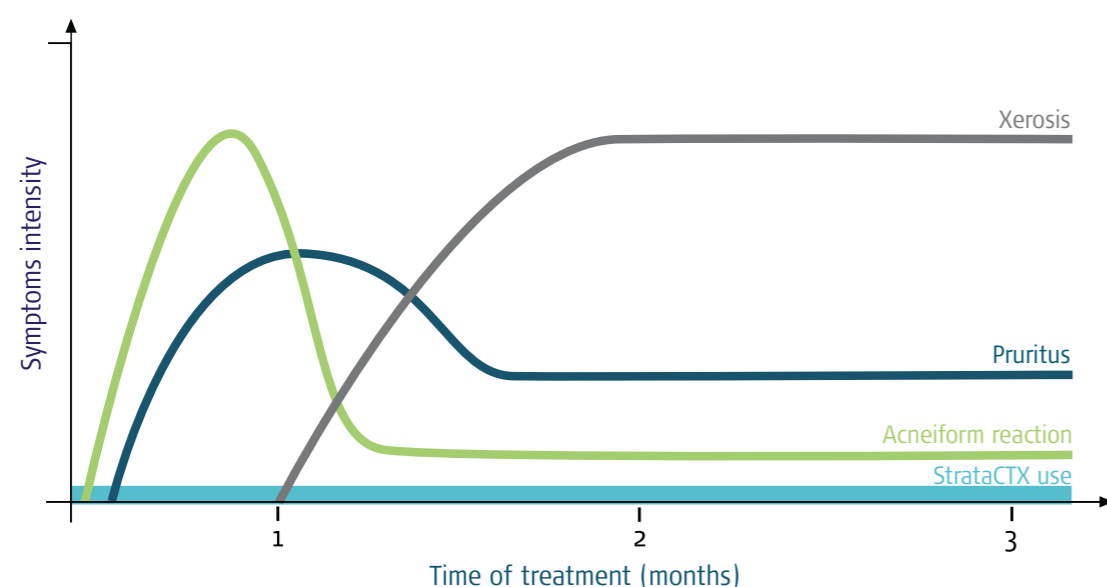
StrataCTX is used to relieve low grade inflammatory changes such as dry, itching, flaking, peeling and irritated skin. For more severe inflammatory changes, StrataCTX reduces pain, redness and heat sensation.

StrataCTX was developed for use on all types of wounds, toxic and compromised skin including:

- Cutaneous reactions
- Pruritic, itchy skin
- Xerotic, dry skin
- Desquamation
- Fissures of skin and nail folds
- Blisters
- Medical Adhesive-Related Skin Injuries (MARSIs)
- Erythema
- Infusion reactions
- Rashes, including: maculopapular rash, hand-foot syndrome, GVHD, acneiform reaction, peri- and appendageal (hair follicles, sweat glands)

Progression of symptoms and cutaneous reactions^{4,5}

When undergoing EGFRI therapy the likelihood of experiencing cutaneous reactions is very high. Below is a visual representation of the progression of such reactions over several months.



Why is StrataCTX an innovative product?



FILM-FORMING GEL

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



FASTER WOUND HEALING

StrataCTX promotes a moist healing environment leading to faster re-epithelialisation.



SYMPTOMATIC RELIEF

StrataCTX provides symptomatic relief from dry, itching, flaking, peeling and irritated skin, and reduces pain, redness and heat sensation.



HYDRATION

StrataCTX is semi-occlusive and gas permeable, which allows the compromised skin and superficial wounds to breathe and remain hydrated.



PROTECTION

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



NON-REACTIVE

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



FOR DIFFERENT AREAS

StrataCTX is suitable for large surface areas and contoured skin like head, face, hand and foot, as well as joints and hairy areas without the need for shaving.



SECONDARY DRESSINGS

Once dry, StrataCTX does not inhibit secondary dressings or adhesives from sticking to the skin surface.



TRANSPARENT

StrataCTX is transparent and is not absorbed through the skin. It is suitable for monitoring the skin condition without the need of having to remove a physical dressing or adhesive.



LIGHTLY BONDS

StrataCTX lightly bonds to the most superficial damaged skin layer.



EASY TO USE

StrataCTX is easy to apply by patients at home.



Clinical evidence with StrataCTX



Start of treatment with StrataCTX



After 5 days of treatment with StrataCTX



Start of treatment with StrataCTX



After 14 days of treatment with StrataCTX



Children's Health Queensland Hospital and Health Service

Children's Health Queensland Hospital and Health Service, Australia

Case series with 12 pediatric patients with Medical Adhesive-Related Skin Injuries (MARSIs)⁹

- All patients experienced MARSIs secondary to central venous access devices (CVAD) dressings.
- Resolution of the skin injuries was observed in all 12 patients in 14 days or less.
- Patients and carers reported less pruritus and irritation using the StrataCTX.
- The fast resolution of these cases is thought to be due to the gel lightly bonding to the contours of the skin providing 24 hour full contact instead of sitting on top. This significantly reduces acute inflammatory responses and promotes faster healing.



Start of treatment with StrataCTX



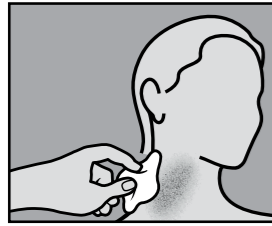
After 14 days of treatment with StrataCTX

Treatment of severe cutaneous reactions induced by topical imiquimod¹³

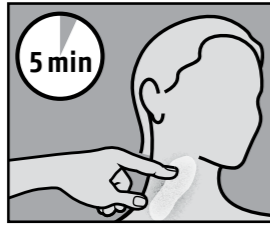
Dr. Rafael Salido Vallejo, Hospital Universitario Reina Sofía. Córdoba, Spain

- Local inflammation on the scalp persisted causing great pain and social isolation for the patient.
- It is known that superficial skin erosions and ulcerations arising from local responses to topical treatments have a high probability of causing permanent sequelae.
- Full recovery occurred 3 months after treatment start.

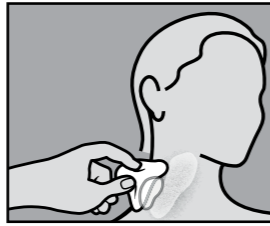
Directions for use



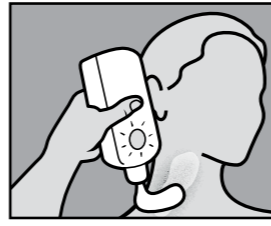
1. Ensure that the affected superficial area is clean and dry.



2. Apply a **very thin layer** of StrataCTX directly to the affected area and allow the gel to dry. When applied correctly, StrataCTX 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, StrataCTX may be covered with sunscreen, cosmetics and clothing.

Additional directions

- StrataCTX should be applied **at least twice daily** to affected areas, as needed or as required to maintain contact with the affected surface.
 - StrataCTX may be re-applied **more often** to ensure constant contact with the skin, or to reduce symptoms.
 - Washing will likely remove StrataCTX. Re-apply StrataCTX **after each wash**.
 - Areas with **higher hygienic necessities** (groin, perineum, anal): StrataCTX should be applied after each urination and bowel movement, on dry and clean skin.
 - For best results StrataCTX should be maintained in **continuous contact** with the skin (24 hours a day/7 days a week).
- StrataCTX can be used with or without a secondary protective dressing.
- StrataCTX **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.
- StrataCTX can be applied directly to the skin, using the finger, Q-tip etc.

Tips for using StrataCTX

- StrataCTX may be stored in the refrigerator prior to application for faster relief of symptoms.
- If not completely dry, StrataCTX 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.

StrataCTX and other products

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

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

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

IMPORTANT

Due to StrataCTX's semi-permeable nature:

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

How much StrataCTX is needed?

StrataCTX gel is an advanced formulation that requires **substantially less product** per application than typical moisturising creams or gels.



StrataCTX 20g

enough to treat an area of 36 × 15 cm
twice per day for over 10 days



StrataCTX 50g

enough to treat an area of 36 × 15 cm
twice per day for over 25 days

Recommended duration of treatment

StrataCTX is recommended to be applied following the first day of treatment, or the first signs or symptoms on the skin and should be applied until resolved or until no further improvement is seen.

StrataCTX - a non-steroidal gel for the management of dry skin and cutaneous rashes

StrataCTX:

- Significantly reduces the skin's acute inflammatory response
- Reduces pain, redness and heat sensation
- Relieves dry, itching, flaking, peeling and irritated skin
- Promotes faster healing
- Hydrates and protects all types of rash and compromised skin
- Is bacteriostatic, reduces the risk of infection
- Is inert, contains no alcohol, parabens or fragrances



www.stratactx.com

Caution: Always read the label, use only as directed. For external use only. StrataCTX should not be placed in contact with the eyes. StrataCTX should not be applied over topical medications unless advised by your physician. StrataCTX 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. StrataCTX does not require special disposal methods. Please follow your local disposal regulations. Sterile until opened.
Ingredients: Polydimethylsiloxanes, siloxanes, alkylmethyl silicones.

References: 1. Bensadoun, R., et al. (2013). *Cancer management and research*, 5, pp. 401-408. 2. Segaert, S., Van Cutsem, E. (2005). *Annals of oncology*, 16(9), pp. 1425-1433. 3. Lacouture, M., et al. (2011). *Supportive care in cancer*, 19(8), pp. 1079-1095. 4. Beech, J., et al. (2018). *Future Oncology*, 14(24), pp. 2531-2541. 5. Chularojanamontri, L., et al. (2019). *Asian Pacific Allergy Immunology*, 37(1), pp. 12-18. 6. Perez-Soler, R., et al. (2005). *The oncologist*, 10(5), pp. 345-356. 7. Inokuchi, M., et al. (2014). *Oncology Letters*, 7(2), pp. 444-448. 8. Gomez, P., Lacouture, M. (2011). *The oncologist*, 16(11), pp. 1508-1519. 9. Shergold, J., Poster presented at Australian and New Zealand Children's Hematology/ Oncology Group (ANZCHOG) Annual Scientific Meeting, Jun 15 -17, 2017, Adelaide, Australia. 10. Riddell, S., Appelbaum, F. (2007). *PLoS Med*, 4(7), e198. 11. Encyclopaedia: Blisters. NHS Direct Wales. <https://www.nhsdirect.wales.nhs.uk/encyclopaedia/b/article/blisters/>. Published 2019. Accessed July 1, 2019. 12. Szepletowski, J. (2014). *Nephrology Dialysis Transplantation*, 19(11), pp. 2709-2712. 13. Data on file, 2016 (Hospital Universitario Reina Sofia. Córdoba, Spain). Stratpharma AG.

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