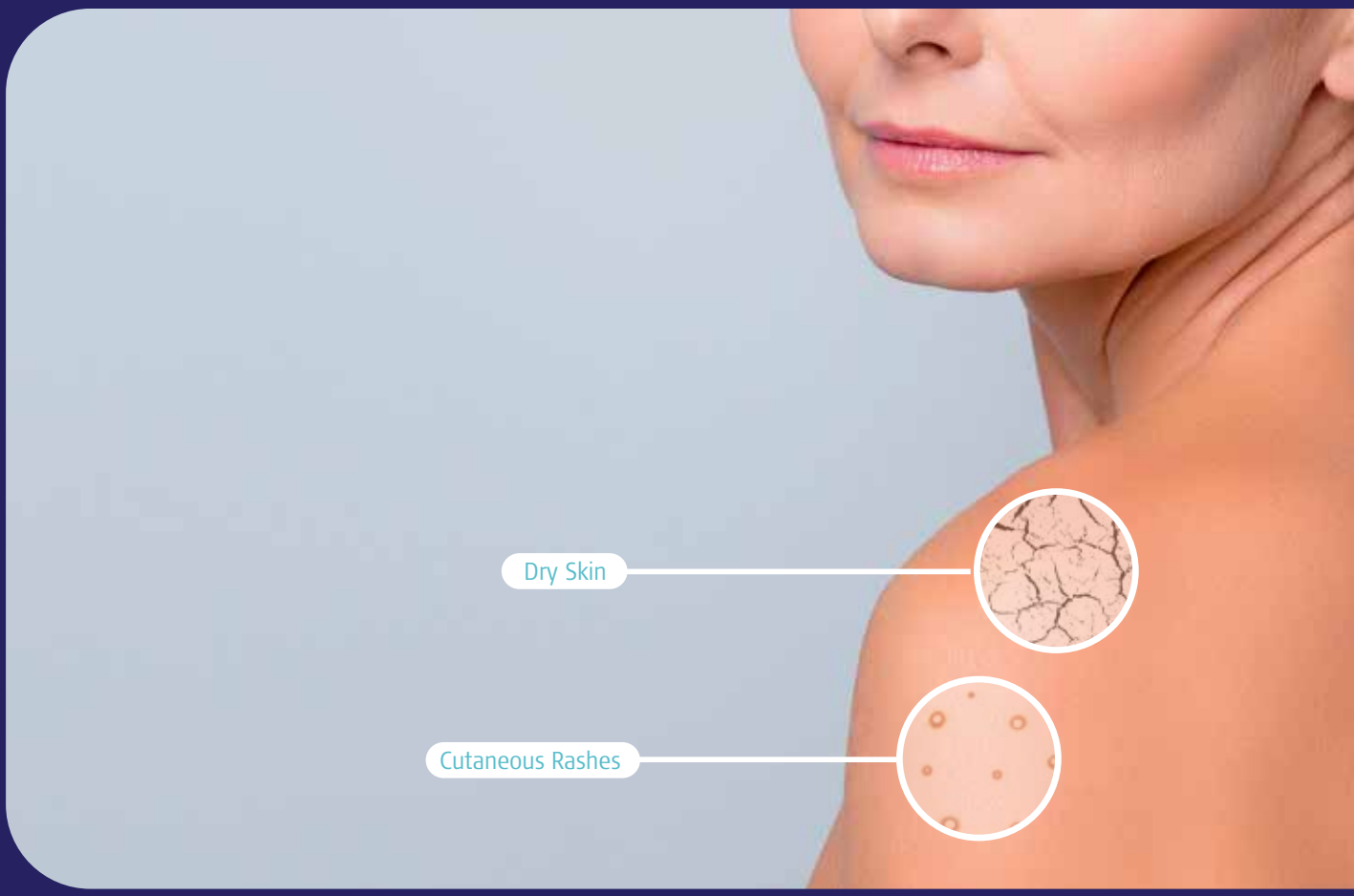
℞ Only
For topical use only
73661-421-50

ADVANCED FORMULATION
Strata ctx®
for cutaneous reactions

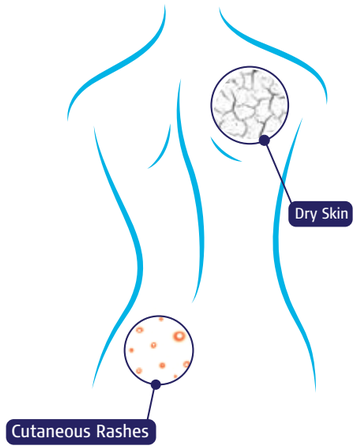
A non-steroidal gel for the management of dry skin and cutaneous rashes



Stratpharma
Switzerland

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

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]

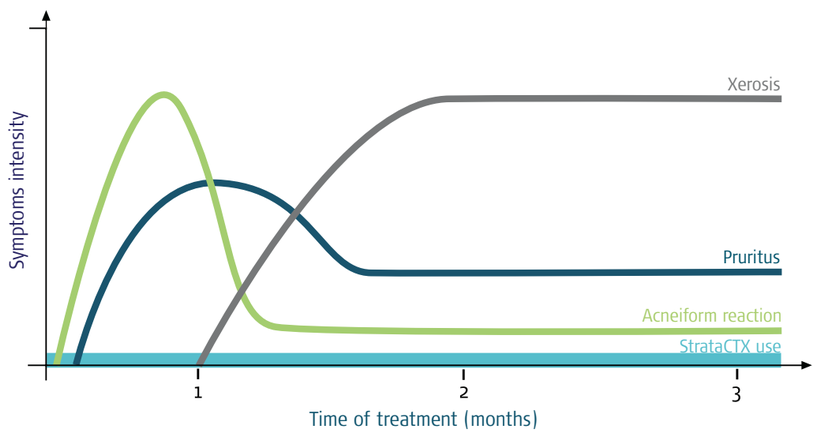
Cutaneous reactions can have a **negative effect** on a patient's **physical, functional, emotional and social well-being**, and could represent a threat to patient **treatment compliance**.[1,2]

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]

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.

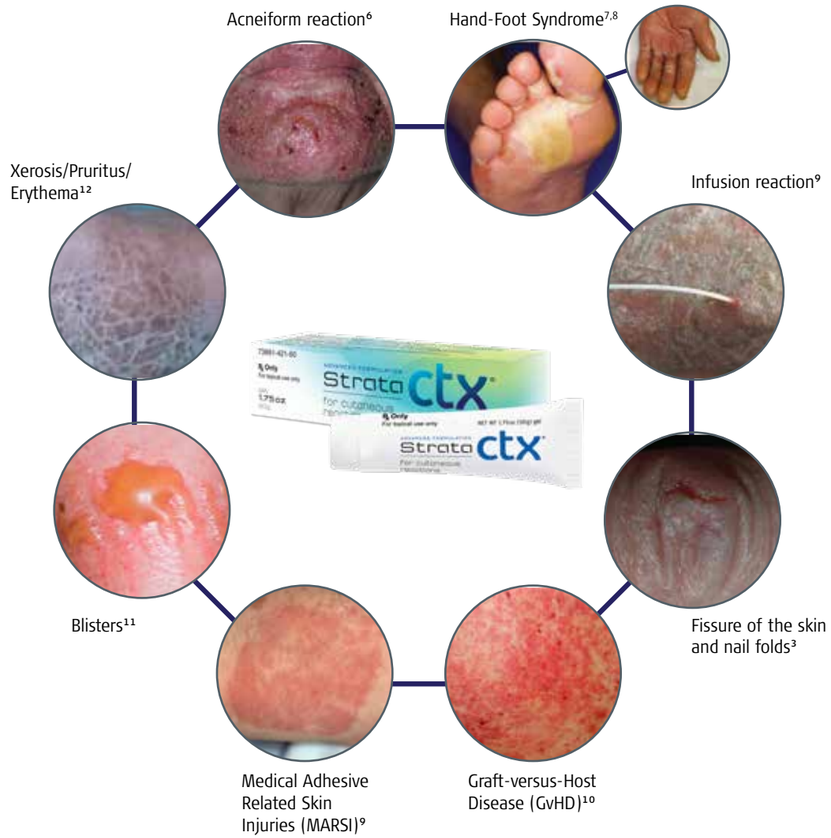


StrataCTX indications

StrataCTX is intended to be used under the direction of healthcare practitioners in the management of cutaneous reactions.

StrataCTX is indicated 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 (MARSI)
- Erythema
- Infusion reactions
- Rashes, including: maculopapular rash, hand-foot syndrome, GVHD, acneiform reaction, peri - and appendageal (hair follicles, sweat glands)



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-epithelialization.

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

HYDRATION
StrataCTX is semi-permeable, which allows the skin 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 steriods, 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.

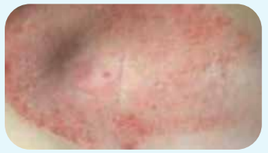
SECONDARY DRESSINGS
Once dry, StrataCTX does not inhibit secondary dressings or adhesives from sticking to the skin surface.

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.

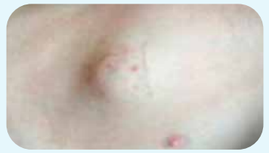
LIGHTLY BONDS
StrataCTX lightly bonds to the most superficial damaged skin layer.

EASY TO USE
StrataCTX is easy to apply by patients at home.

Clinical evidence with StrataCTX



Start of treatment with StrataCTX

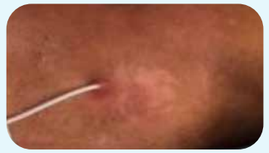


After 5 days of treatment with StrataCTX

Children's Health Queensland Hospital and Health Service

Children's Health Queensland Hospital and Health Service, Australia

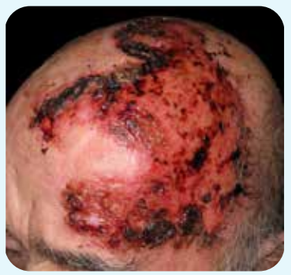
Start of treatment with StrataCTX



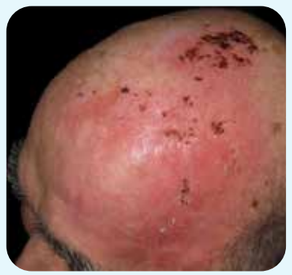
After 14 days of treatment with StrataCTX

Case series with 12 pediatric patients with Medical Adhesive-Related Skin Injuries (MARSI)[9]

- All patients experienced MARSI 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 hours 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 imiquimod[13]

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.

Dosage and Administration

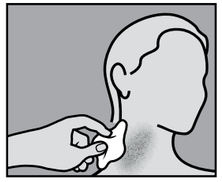
StrataCTX gel is an advanced formulation that requires **substantially less gel** per application than typical creams or gels.

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

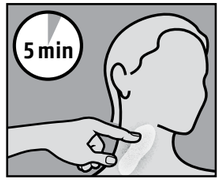
How supplied

StrataCTX 1.75oz (50g) tube (73661-421-50)

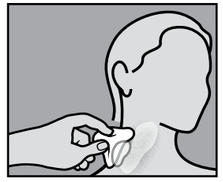
Directions for use



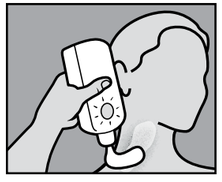
1. Ensure that the affected superficial area is clean and dry.



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

Moisturizers, 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 moisturizer can be applied after StrataCTX dries to maintain the first contact of StrataCTX with the skin.

StrataCTX reduces the need for corticosteroids or antibiotics.
StrataCTX reduces skin's acute inflammatory response without side effects of corticosteroids or 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 adsorption of active ingredients if that are applied over StrataCTX.

Additional prescribing information

Therapeutic group: Wound dressing for the management of cutaneous reactions.

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

Description: When used as directed StrataCTX 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. StrataCTX helps to promote a moist healing environment. This moist wound healing environment promotes faster re-epithelialization* and reduces the skin's acute inflammatory response.

Warnings: 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.

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 StrataCTX.

Drug interactions: None known.

Use in specific populations: No specific population restrictions, StrataCTX 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 ctx®
for cutaneous reactions

℞ Only
For topical use only
73661-421-50

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
- Relives 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

To attend Educational Webinars, request samples, or if you have questions about Stratpharma products, prescriptions, supply, etc. 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.stratactx.com

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

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. (2018). *Asian Pacific J Allergy Immunology*. 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 Scientifc 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. Szepietowski, J. (2014). *Nephrology Dialysis Transplantation*, 19(11), pp. 2709-2712. 13. Data on file, 2016 (Hospital Universitario Reina Sofía. Córdoba, Spain). Stratpharma AG.

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Class I Medical Device

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Distributed by: Marnel Pharmaceuticals LLC Charleston, SC 29403, U.S.A. 1-833-788-0312

Stratpharma Switzerland

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