

Rx Only

For topical use only

73661-421-50

ADVANCED FORMULATION

Strata

ctx[®]

for cutaneous reactions

Professional non-steroidal support for your skin



 **Stratapharma**
Switzerland

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

What are cutaneous reactions?

Cutaneous reactions are damages of the skin, nail and hair follicles. The reactions are thought to be due to a disruption of the skin barrier function causing dehydration and an inflammation of the follicles and skin. The skin becomes more sensitive to allergens and sunlight and is prone to infection.¹

Therapies which cause a wide range of cutaneous reactions are **chemotherapy and immunotherapy**. They can cause problems such as dry, itchy, red, and/or peeling skin. Some people may develop a rash or sun sensitivity. Nail changes can develop which include dark, yellow, or cracked nails and/or cuticles that are red and hurt.^{2,3}

Some oncology drugs, such as Epidermal Growth Factor Receptor Inhibitors (EGFRI), are responsible for rashes in as many as **80% of patients**, of which some can be **severe**.⁴

Skin reactions may lead to medication dose changes or even discontinuation of the treatment if severe. For this reason **effective treatment** is essential.⁴

Skin reactions can have a **negative effect** on a person's physical, functional, emotional, and social well-being.¹

Common skin reactions are:

- Dry skin/ itching/ redness
- Blisters
- Fissures (cracks) of the skin and nails
- Hand-Foot Syndrome (HFS)
- Infusion Reaction
- Graft-versus-Host Disease (GVHD)
- Medical Adhesive Related Skin Injuries (MARS)

Side effects may worsen if unsuitable products are used.¹

It is paramount to maintain the skin barrier function, protect the skin, hydrate the affected area and keep the skin free from infection.¹

Take care of your skin

There are no international guidelines on the care of dry skin and rashes, but the following recommendations are widely accepted:^{1,5}

- Use mild soap and unperfumed detergents.
- Avoid direct sunlight and use sunscreen with at least SPF 30+.
- Regularly hydrate the skin, hands and feet with an alcohol free, unperfumed moisturizer that does not contain added vitamins or active ingredients.
- Avoid creams and anti-acne medications, creams with fruit acids, antibacterial properties and benzoyl peroxide. They may irritate the skin and can even be harmful.
- Avoid activities and products that may rub on the skin such as: backpacks, ties, belts, and accessories/ jewellery. Wear comfortable and breathable clothing.
- Do not wet-shave or walk barefoot to avoid skin irritations. Be careful when trimming nails.
- Avoid temperature extremes (hot showers, excessive sun exposure and hot or cold air).

When do I need to see a doctor?⁶

If you are on medication and you develop a skin reaction you will need to inform your treating team immediately.

If you are not undertaking therapy, there are some symptoms that can imply that a skin reaction requires medical attention. If you have symptoms such as a fever, a suddenly occurring and rapidly spreading rash, swelling, blistering, pain or signs of infection, seek immediate medical attention.

StrataCTX – professional support for your skin

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 (MARS)
- Erythema
- Infusion reactions
- Rashes, including: Maculopapular rash, hand-foot syndrome, GVHD, acneiform reaction, peri- and appendageal (hair follicles, sweat glands)

StrataCTX 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. StrataCTX is a flexible, film-forming wound dressing in a gel format.



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 wound healing.



HYDRATION

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



PROTECTION

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

Clinical evidence with StrataCTX

Pediatric patients with a dressing-related skin reaction.⁷



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



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

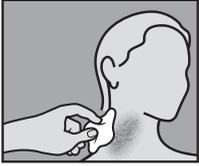
StrataCTX is suitable for large surface areas and contoured skin like head, face, hand and foot, as well as joints and hairy areas without the need for shaving.



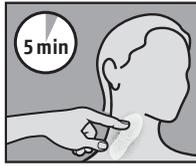
EASY TO USE

StrataCTX is easy to apply by patients at home.

How to apply StrataCTX



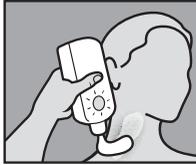
1. Ensure that the affected superficial area is clean and dry.



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 is recommended to be applied following the first day of treatment, or the first signs or symptoms on the skin and should be used until resolved or until no further improvement is seen.
- StrataCTX **does not need to be rubbed in or massaged**, as it does not penetrate through the skin 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 for faster relief of symptoms.
- If not completely dry, StrataCTX may stain clothing. Normal washing will not remove the product from your clothes. If staining occurs, dry cleaning should be able to remove it without damaging the fabric.
- **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.

Dosage and administration

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



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

Warnings and Contraindications

Warning: 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.

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



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

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

References: 1. Bensadoun, R., et al. (2013). *Cancer management and research*, 5, pp. 401-408. 2. National Cancer Institute (2019). *Skin and Nail Changes*. Available at: <https://www.cancer.gov/about-cancer/treatment/side-effects/skin-nail-changes>. Accessed: June 3, 2019. 3. Lacouture, M., et al. (2011). *Supportive care in cancer*, 19(8), pp. 1079-1095. 4. Segaeert, S., Van Cutsem, E. (2005). *Annals of oncology*, 16(9), pp. 1425-1433. 5. Boucher, J., et al. (2011). *J Oncology Nursing*, 15(5), pp. 501-508. 6. American Academy of Dermatology. *Rash in 101 adults: When to seek medical treatment*. Available at: <https://www.aad.org/public/everyday-care/itchy-skin/rash/rash-101>. Accessed: July 9, 2019. 7. Shergold, J., Poster presented at Australian and New Zealand Children's Hematology/ Oncology Group (ANZCHOG) Annual Scientific Meeting, Jun 15-17, 2017, Adelaide, Australia.

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