

StrataCTX is a non-steroidal, full contact, flexible wound dressing for the management of dry skin and cutaneous reactions.



Visit our website for more information about StrataCTX and the care of cutaneous reactions.

www.stratactx.com

Caution: 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. For correct storage please reclose the tube tightly with the cap. Should your cutaneous reaction show signs of infection or failure to heal, immediately consult your physician. If irritation occurs, discontinue use and consult your physician. Not suitable for highly exudative wounds, tunneling wounds or 3rd degree burns. 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. **Sterile until opened.** **Ingredients:** Polydimethylsiloxanes, siloxanes, alkylmethyl silicones

References: 1. Bensadoun R, Humbert P, Krutmann J et al. Daily baseline skin care in the prevention, treatment, and supportive care of skin toxicity in oncology patients: recommendations from a multinational expert panel. *Cancer Manag Res.* 2013;401. 2. Skin and Nail Changes. National Cancer Institute. <https://www.cancer.gov/about-cancer/treatment/side-effects/skin-nail-changes>. Published 2019. Accessed June 3, 2019. 3. Lacouture M, AnadkatM, BensadounR et al. Clinical practice guidelines for the prevention and treatment of EGFR inhibitor-associated dermatologic toxicities. *Supportive Care in Cancer.* 2011;19(8):2079-1095. 4. SegarT, Van CutsemE. Clinical signs, pathophysiology and management of skin toxicity during therapy with epidermal growth factor receptor inhibitors. *Ann Oncol.* 2005;16(9):1425-1433. 5. How to tell if a rash needs medical attention | American Academy of Dermatology. [aad.org/media/news-releases/how-to-tell-if-a-rash-needs-medical-attention](https://www.aad.org/media/news-releases/how-to-tell-if-a-rash-needs-medical-attention). Published 2019. Accessed July 9, 2019. 6. Boucher J, Olson L, Piperdi B. Preemptive Management of Dermatologic Toxicities Associated With Epidermal Growth Factor Receptor Inhibitors. *Clin J Oncol Nurs.* 2011;15(5):501-508 7. ShergoldJ. Managing medication adhesive related skin injuries (MARSi) due to central venous access device (CVAD) dressings using a novel silicone gel wound dressing. Poster presented at: Jun 15 -17, 2017; Australian and New Zealand Children's Hematology/ Oncology Group (ANZCHOG) Annual Scientific Meeting; Adelaide, Australia.

CE Class IIa Medical Device
FDA Listed

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Tips for using StrataCTX

StrataCTX may be stored in the refrigerator for a cooling effect which relieves the burning sensation.

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.

How much StrataCTX do I need?

StrataCTX gel is an advanced formulation that requires substantially less gel per application than typical moisturizing creams or barrier ointments. A little bit goes a long way. StrataCTX does not soak into the skin. It dries to form a very thin protective layer on top of the skin.

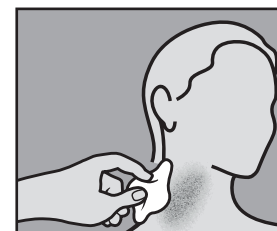


StrataCTX 20 g (0.7 oz) is enough to treat an area of 36x15cm (14x6 in), twice per day for over 10 days.

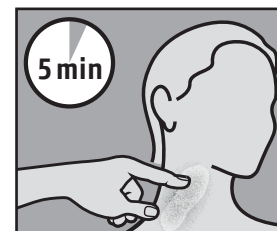
StrataCTX 50 g (1.75 oz) is enough to treat an area of 36x15cm (14x6 in), twice per day for over 25 days.

Gently spread the gel on the skin, nail beds or crevices.

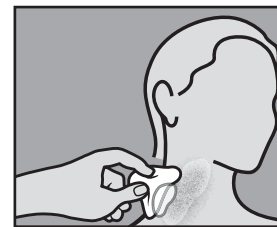
How to apply StrataCTX



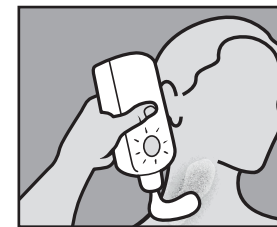
1. Ensure that the affected superficial area is clean and dry.



2. Apply a very thin layer of StrataCTX directly to the affected area and allow the gel to dry. It 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.

StrataCTX should be applied at least twice daily to affected areas, as needed or as advised by your physician.

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 (24 hours a day/7 days a week) or until no further improvement is seen.

StrataCTX can be applied more frequently to relieve itching or other symptoms.



Professional support for your skin

What are cutaneous reactions?

Cutaneous reactions are toxicities 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 chemo- 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}

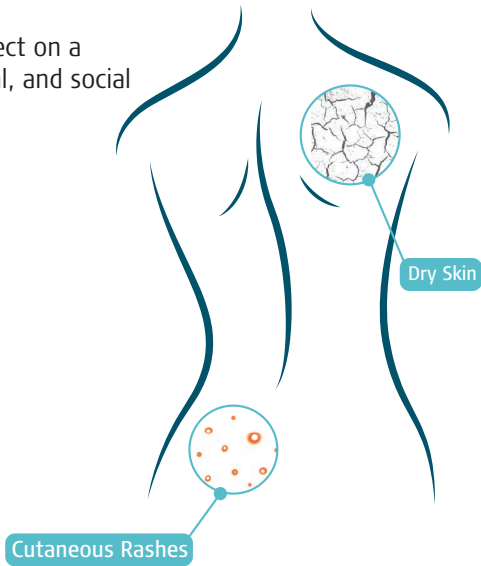
Some oncology drugs, such as Epidermal Growth Factor Receptor Inhibitors (EGFRI), are responsible for rashes in as many as 80% of patients, of which some can be severe.⁴

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

Side effects may worsen if unsuitable products are used.¹

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



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 (MARSI)

When do I need to see a doctor?⁵

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.

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, 6}

- Use mild soap and unperfumed detergents.
- Avoid direct sunlight and use sunscreen with 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 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).



StrataCTX – professional support for your skin

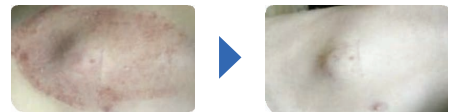
StrataCTX is a flexible, film-forming wound dressing in a gel format.

StrataCTX dries to form a thin and protective layer which maintains the skin barrier and creates an optimal environment for faster healing. It relieves low grade inflammatory changes such as dry, itching, flaking, peeling and irritated skin. StrataCTX also reduces pain, redness and heat sensation.

Therefore, a professional treatment with StrataCTX decreases the risk of dose modifications or treatment breaks.

Clinical evidence with StrataCTX

Pediatric patient with a dressing related skin reaction.⁷



Before treatment

Day 5

- StrataCTX protects the skin and promotes faster healing.
- StrataCTX hydrates the skin and reduces the risk of infection.
- StrataCTX can be applied from the first day of treatment, as prevention from skin toxicity or from the first sign of a skin reaction.
- StrataCTX is transparent, does not contain steroids, alcohol, parabens or fragrances.
- StrataCTX is ideal for large and contoured areas such as the head, face, hands and feet, joints and hairy areas without the need for shaving.
- StrataCTX was developed in order to be spread easily using a very small amount of gel.
- StrataCTX is easy to apply at home.