ADVANCED FORMULATION

Strata ctx®

Gel for dry skin and cutaneous rashes

Dry Skin

Cutaneous Rashes

A full contact flexible wound dressing for the management of dry skin and cutaneous rashes

Stratpharma
Switzerland

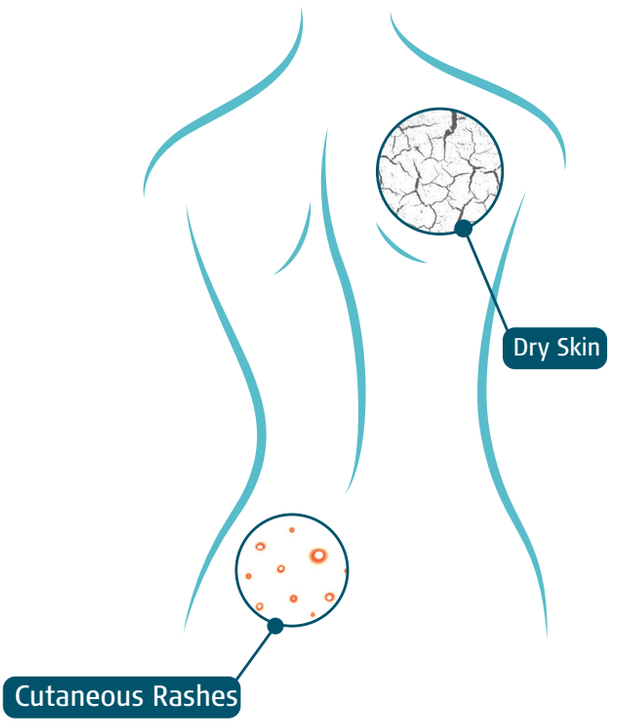
Cutaneous rashes – etiology

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

For instance, oncology drugs are experiencing a breakthrough with the development of new targeted therapies, however at the expense of cutaneous side effects. Some oncology drugs, such as Epidermal Growth Factor Receptor Inhibitors (EGFRI) are responsible for rashes in 80% of patients, of which 10 – 17% can be severe.[1]

The goal is to reduce symptoms, so that the patient is able to comply with the therapy plan. Some cutaneous reactions may limit the use of medications due to a negative impact in the patients' quality of life.[2]

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 paramount to maintain the skin barrier function using appropriate products and to control the severity of the signs and symptoms of cutaneous side effects.

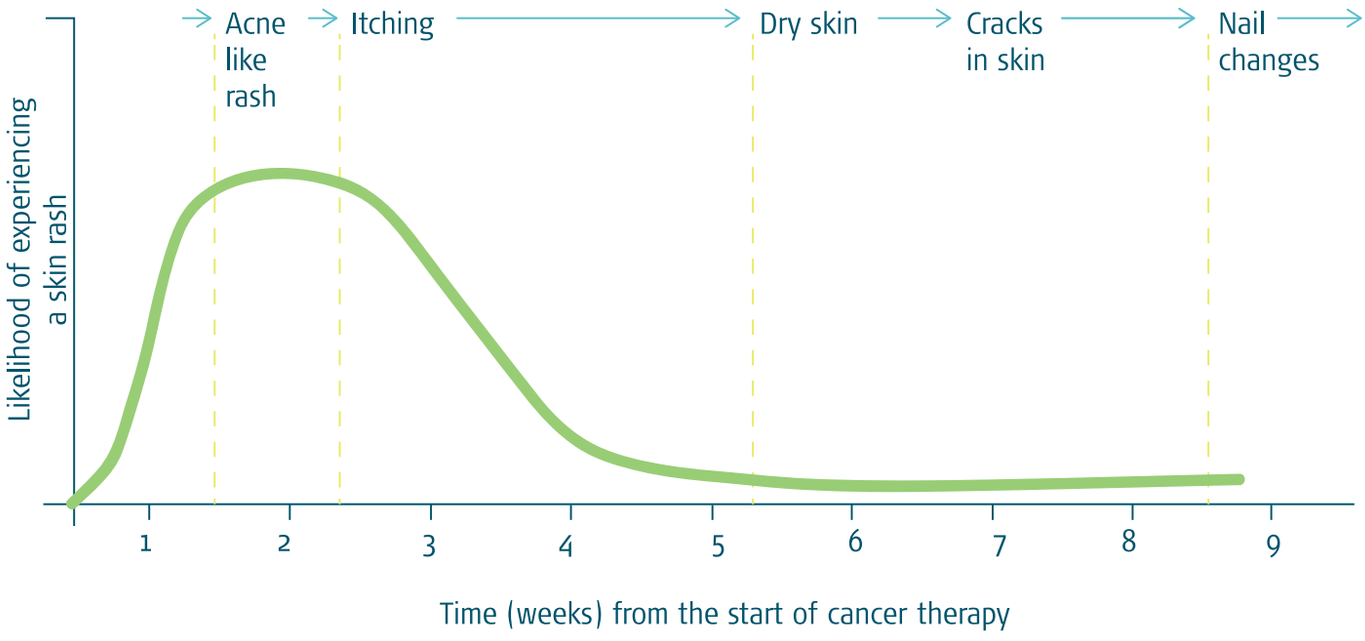


Common signs and symptoms of cutaneous reactions[3]:

- Pruritic / itchy skin
- Xerotic / dry skin
- Fissure of the skin and nail folds
- Blisters
- Erythema / redness
- Hand-Foot Syndrome (HFS)
- Graft-versus-Host Disease GvHD
- Acneiform reaction
- Maculopapular rash
- Alopecia

Progression of symptoms and cutaneous reactions[4]

Below is a graphical representation of the progression of cutaneous reactions over the weeks. These are especially likely to happen if undergoing EGFRI therapy.



CTCAE – severity and classification standard[5]

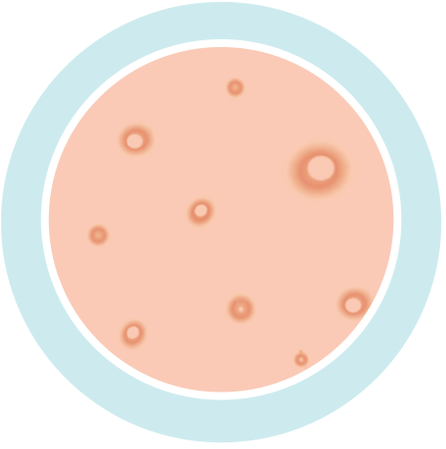
The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each Adverse Event (AE) based on this general guideline, V5.0[5]:

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms. Only observations needed and no intervention of physician indicated.	Moderate symptoms. Minimal local or noninvasive intervention of physician indicated.	Severe or medically significant symptoms, but not immediately life-threatening. In a common case hospital-ization or prolongation of hospitalization indicated. It limits self-care possibility and regular lifestyle.	Life-threatening consequences of symptoms. Urgent physician's intervention indicated.	Death related to AE (not applicable for all Adverse Events).

Between 30 and 50%[6] of patients with side effects report their occurrence as the reason for discontinuation of treatment.[6]

Recommended treatment options for rashes

Patients are frequently advised to use non-reactive skin care and sunscreen.[7]



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. Topical steroids are usually recommended, but have shown to be ineffective in patients suffering from severe rashes.[8]

Acne products are not effective in the treatment of drug rashes and may worsen other symptoms like burning sensation, pain and irritation.[8]

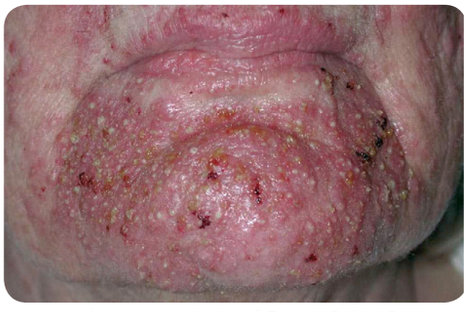
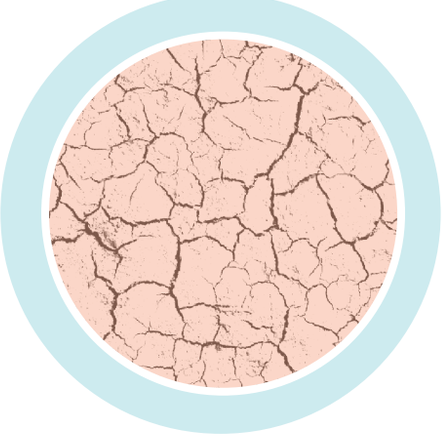


Image courtesy of Perez-Soler, R.

Recommended treatment options for xerosis

If xerosis happens on hands or feet, patients may develop painful fissures on the dorsal sides of the interphalangeal joints.[9]



Preventative measures like avoiding soaps, limiting shower time, using lukewarm water, and frequent use of emollients are often recommended.

Moderate to potent steroids are the preferred option when xerosis is moderate.[10]

Uninterrupted use of topical steroids can cause dermal toxicity and increase the risk of infection and should not be used over 14 days.[11]

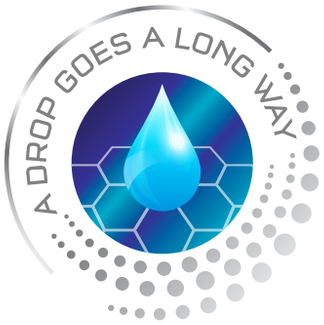
In the case of xerosis secondary to EGFRI therapy, antibiotics are sometimes used. Doxycycline is often used, but it is a strong photosensitizer. Tacrolimus is contraindicated in immunosuppressed patients.[1]

StrataCTX – a new approach for managing xerotic skin and rashes

- 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 burning sensation.
- When used as directed, StrataCTX dries to form a protective layer that is gas permeable and waterproof. This hydrates and protects compromised skin areas and superficial wounds from chemical and microbial invasion.
- StrataCTX is a self-drying, non-sticky gel formulation that lightly bonds to the most superficial damaged skin layer.
- StrataCTX helps to promote a moist healing environment for wounds or compromised skin. This moist wound healing environment promotes faster re-epithelialization and significantly reduces the skins acute inflammatory response.

How much StrataCTX is required

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 20 g (0.70 oz) is enough to treat an area of 36 × 15 cm, (14 × 6 inch) twice per day for over 10 days.

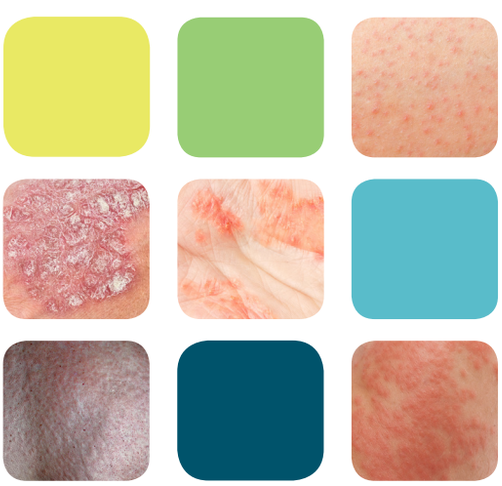
StrataCTX 50 g (1.75 oz) is enough to treat an area of 36 × 15 cm, (14 × 6 inch) twice per day for over 25 days.

Why is StrataCTX an innovative wound dressing?

- StrataCTX is a film-forming wound dressing in gel format adapting to any surface before drying into a protective sheet.
- StrataCTX provides relief of symptoms such as itchiness, tenderness, dryness, burning sensation, without using steroids.
- StrataCTX improves severe signs such as erythema, erosions, fissures and swelling without using active pharmaceuticals.
- StrataCTX can also be used for infusion reactions and to avoid Medical Adhesive-Related Skin Injuries (MARSI).
- StrataCTX is a medical device class IIa.
- StrataCTX is transparent allowing monitoring the therapy progress without removal of the dressing.

StrataCTX in the management of dry skin and cutaneous rashes

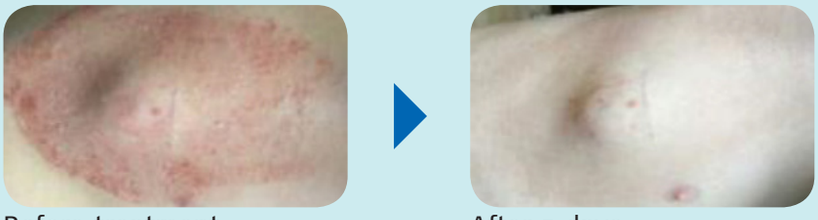
StrataCTX is used for cutaneous reactions, like eruptions, hand-foot syndrome and its symptoms, like itching and dryness, with the following therapeutic goals:



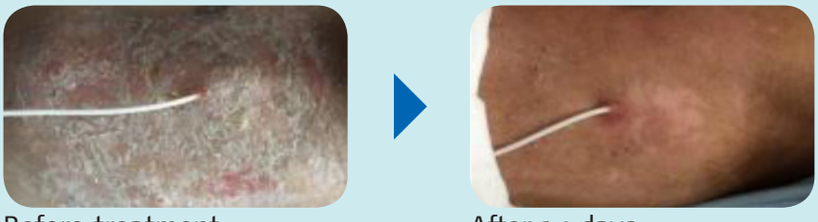
- Faster re-epithelialization of the skin
- Relief of low grade cutaneous changes such as dry, itching, flaking, peeling and irritated skin
- Reduced pain, redness and heat, while helping to soothe exposed areas in more severe inflammatory changes
- Preservation of the skin integrity
- Optimization of the environment for the reparative process
- Reducing the risk of infection

StrataCTX – clinical evidence

Children's Health Queensland Hospital and Health Service



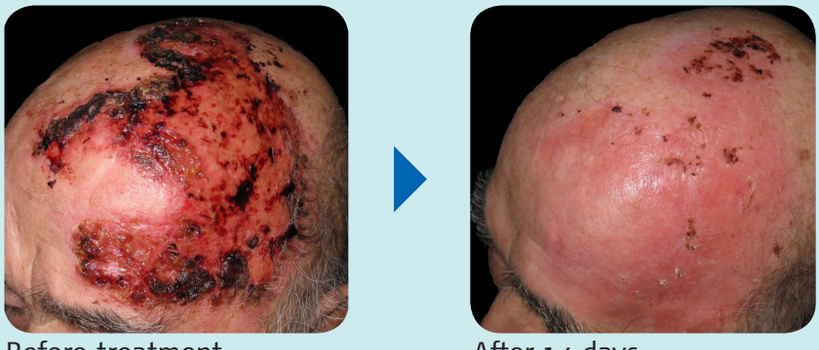
Before treatment | After 5 days



Before treatment | After 14 days

Case series[12] with 14 pediatric patients with infusion reactions

- 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.



Before treatment | After 14 days

Treatment of severe cutaneous reactions induced by topical imiquimod[13]

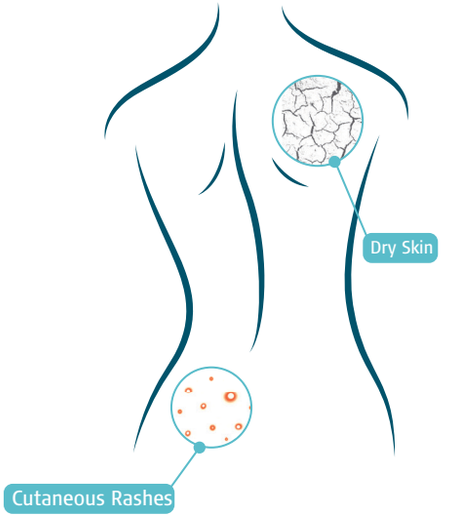
- Local inflammation on the scalp persisted causing great pain and social isolation for the patient.
- It is known that superficial skin erosions and ulcerations arising from local responses to topical treatments have a high probability of causing permanent sequelae.
- Full recovery occurred 3 months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

A flexible wound dressing for the management of dry skin and cutaneous rashes

- Sterile, biologically inert and bacteriostatic
- Full contact flexible wound dressing
- Lightly bonds to the most superficial damaged layer of the skin
- Reduction of acute inflammatory response
- Waterproof, gas permeable and hydrating
- For best result keep in contact with the skin
- Compatible with secondary dressings
- Transparent – allows easy therapy monitoring

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



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

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. 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. 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. **Ingredients:** Polydimethylsiloxanes, siloxanes, alkylmethyl silicones. **STERILE UNTIL OPENED.**

References: 1. Lacouture M, Anadkat M, Bensadoun R et al. Clinical practice guidelines for the prevention and treatment of EGFR inhibitor-associated dermatologic toxicities. Supportive Care in Cancer. 2011;19(8):1079-1095. doi:10.1007/s00520-011-1197-6 2. Štulhofer Buzina D, Martinac I, Ledić Drvar D, Čeović R, Bilić I, Marinović B. The Most Common Cutaneous Side Effects of Epidermal Growth Factor Receptor Inhibitors and Their Management. - PubMed - NCBI. Ncbi.nlm.nih.gov. https://www.ncbi.nlm.nih.gov/pubmed/26724881. Published 2015. Accessed January 16, 2019. 3. Puig L, Gulliver W (eds): Adverse Reactions to Biologics. Curr Probl Dermatol. Basel, Karger, 2018, vol 53, pp 93-104 4.Segaert S, Van Cutsem E. Clinical signs, pathophysiology and management of skin toxicity during therapy with epidermal growth factor receptor inhibitors. Ann Oncol. 2005;16(9):1425–1433 5. Common Terminology Criteria for Adverse Events (CTCAE). Ctep.cancer.gov. https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Published 2017. Accessed January 16, 2019. 6. Costa F, Mil J, Alvarez-Risco A. The Pharmacist Guide To Implementing Pharmaceutical Care.; 2019. 7. 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. doi:10.2147/cmar.s52256 8. Perez-Soler R, Delord JP, Halpern A, et al. HER1/EGFR inhibitorassociated rash: future directions for management and investigation outcomes from the HER1/EGFR inhibitor rash management forum. Oncologist. 2005;10(5):345–356 13. Jatoi A, Green EM, Rowland KM Jr, Sargent DJ, Alberts SR. Clinical predictors of severe cetuximab-induced rash: observations from 933 patients enrolled in north central cancer treatment group study N0147. Oncology. 2009;77(2):120–123. 9. Galimont-Collen AF, Vos LE, Lavrijsen AP, Ouwerkerk J, Gelderblom H. Classification and management of skin, hair, nail and mucosal sideeffects of epidermal growth factor receptor (EGFR) inhibitors. Eur J Cancer. 2007;43(5):845–851. 10. Hu JC, Sadeghi P, Pinter-Brown LC, Yashar S, Chiu MW. Cutaneous side effects of epidermal growth factor receptor inhibitors: clinical presentation, pathogenesis, and management. J Am Acad Dermatol. 2007;56(2):317–326. 11. Lynch T, Kim E, Eaby B, Garey J, West D, Lacouture M. Epidermal Growth Factor Receptor Inhibitor-Associated Cutaneous Toxicities: An Evolving Paradigm in Clinical Management. Oncologist. 2007;12(5):610-621. 12. Shergold J. 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. 13. Data on file, 2016 (Hospital Universitario Reina Sofía. Córdoba, Spain). Stratpharma AG.

CE Class IIa Medical Device

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Stratpharma Switzerland

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