

Rx Only
For topical use only
73661-421-50

ADVANCED FORMULATION
Strata **ctx**[®]
for cutaneous
reactions

A non-steroidal gel for the management of
inflammatory skin conditions and cutaneous reactions
Ideal for short- and long-term use



 **Stratapharma**
Switzerland

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

Inflammatory skin conditions and their impact on quality of life

Despite the fact that **skin disorders are the 4th most common cause of all human disease**, affecting over 1/3 of the world's population, their impact is frequently underestimated.¹ **Atopic dermatitis** is one of the most common dermatoses, affecting **up to 30% of children** and persisting into **adulthood in 25%** of cases.²

22 million Americans sought medical treatment for **atopic, contact and seborrheic dermatitis, and psoriasis disorders**. The most common inflammatory skin conditions, costs the US health care system \$3 billion in medical treatments per year.³

Inflammatory skin diseases are a major source of **diminished quality of life** and have an impact on the physical, emotional, and social life of patients and their co-habitants. Beyond the **itch, redness, flaky skin and pain**, these skin conditions can cause **discomfort, embarrassment and frustration**.

The involvement of areas with a high emotional burden, such as the **vaginal area, scalp, or facial area**, might result in **social inhibition, anxiety, and depression**.^{4,5}

Children with inflammatory skin conditions are more likely to experience **stigma, concomitant psychological conditions, and strained family relationships**.⁶

For these patients, it is vital to restore the barrier function of the epidermis and hydrate the affected area, while keeping the skin free from infection or environmental contamination.



Treatment options

Most inflammatory skin diseases are typically treated with topical corticosteroids and/or topical antibiotics. However, when they are used as long-term therapies, local and systemic side effects, as well as antibiotic resistance, are just a few of the challenges physicians and patients may experience.

Topical corticosteroids may cause **local side effects** such as skin atrophy, increase in skin transparency and brightness, telangiectasia, Striae (stretch marks), easy bruising, and **systemic side effects** such as Cushing's syndrome, diabetes mellitus and hyperglycaemia. The use of topical corticosteroids **on the face** can induce eruptions, such as perioral dermatitis, steroidal rosacea and acne.⁷

There is a **growing concern** about contact dermatitis, delayed healing and antibiotic resistance due to unrestricted use of **topical antibiotics**.^{1,8} **75%** of patients use over-the-counter petrolatum-based topical antibiotics **without doctor's prescription**, and **21.6%** of them **develop contact dermatitis**.⁸

StrataCTX, a non-steroidal gel for the effective management of inflammatory skin conditions and cutaneous reactions

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

StrataCTX is used to **relieve low grade inflammatory changes** such as dry, itching, flaking, peeling and irritated skin **without side effects of topical corticosteroids**.

StrataCTX is **bacteriostatic**, reducing the risk of infections and contact dermatitis.

StrataCTX is **non-reactive**, it has no measurable pH, and contains no steroids, alcohol, parabens or fragrances, allowing **long-term use**.

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

StrataCTX is a FDA Registered Class I Medical Device.



StrataCTX indications

StrataCTX is intended to be used under the direction of healthcare practitioners in the management of cutaneous reactions. StrataCTX is designed to adhere gently to existing epidermis making it the **ideal gel** for the management of cutaneous reactions and inflammatory skin conditions.

StrataCTX is indicated for use on all types of wounds, toxic and compromised skin including:

Inflammatory skin conditions and cutaneous reactions:

- Eczema, including: atopic, seborrheic and contact dermatitis
- Psoriasis
- Xerotic (dry) skin, Pruritic (itchy) skin
- Flaky, peeling and irritated skin
- Erythema
- Medical Adhesive-Related Skin Injuries (MARSI)
- Incontinence associated dermatitis and diaper rash



Xerosis (dry) skin
Pruritus (itchy) skin⁹



Atopic dermatitis¹⁰



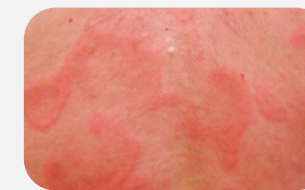
Seborrheic dermatitis⁴



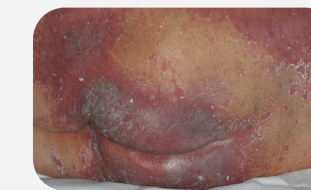
Contact dermatitis¹¹



Psoriasis¹²



Erythema¹³



Incontinence associated dermatitis¹⁴



Medical Adhesive Related Skin Injuries (MARSI)¹⁵

Other medical indications, including upon administration of medications (systemic or topical):

- Blisters
- Acneiform reaction
- Infusion reactions
- Hand-Foot syndrome
- Fissures of skin and nail folds
- Graft-versus-Host Disease (GvHD)
- Peri- and appendageal (hair follicles, sweat glands)



Blisters¹⁶



Acneiform reaction¹⁷

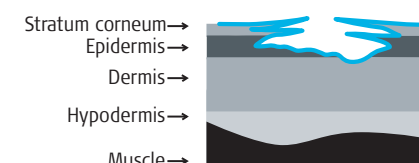


Hand-Foot Syndrome^{18,19}

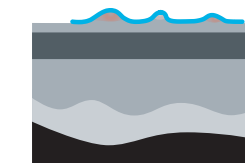


Graft-versus-Host disease (GvHD)²⁰

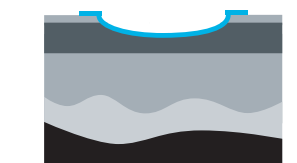
StrataCTX application:



Inflammatory skin conditions



Skin rashes



Superficial wounds and compromised skin

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 for 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

Medical Adhesive-Related Skin Injuries (MARSI)¹⁵



Start of treatment with StrataCTX



After 5 days of treatment with StrataCTX

A pediatric patient that experienced MARSI secondary to central venous access devices (CVAD) dressings.

Children's Health Queensland Hospital and Health Service, Australia



- The fast resolution of the case was thought to be due to StrataCTX lightly bonding to the contours of the skin providing 24 hours full contact. This **significantly reduced** acute inflammatory responses and promoted a faster healing.
- StrataCTX allowed the skin to **maintain a moist, semi-permeable environment**, without causing the abrasion/irritation.
- **Less pruritus and irritation** was observed using StrataCTX.

Erythematous plaques with crusting and ulceration²¹



Start of treatment with StrataCTX



After 14 days of treatment with StrataCTX

An 82-year-old man previously treated for actinic keratoses with imiquimod presented with an intense inflammatory response on the scalp.

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

- Local inflammation on the scalp persisted causing great pain and social isolation for the patient.
- **Major improvement of epithelialization** of all ulcerated areas and minimal superficial scabs were achieved after 2 weeks of treatment with StrataCTX.
- StrataCTX showed efficacy in **preventing the manifestation of abnormal scarring**.

Eczematous chelitis²²



Start of treatment with StrataCTX



After 14 days of treatment with StrataCTX

A 19-year-old patient suffering from chronic relapsing xerotic eczematous chelitis.

Dr. Marini L., Skin Doctors' Center, Trieste, Italy.

Impaired skin barrier function effectively improved due to StrataCTX functional hydrophobic barrier allowing gas permeability and reducing Trans-Epidermal Water Loss (TEWL).

Dosage and Administration

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

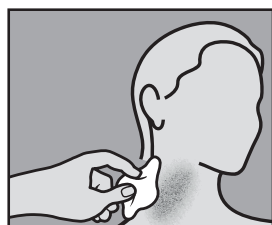
StrataCTX 1.75oz (50g) is enough to treat an area of 6x12 inch (15x30 cm) twice per day for 30 days.



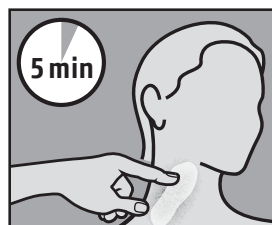
How supplied

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

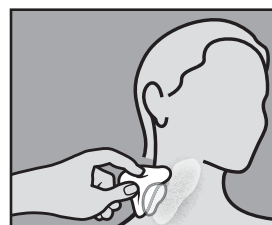
Directions for use



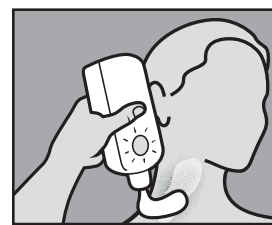
1. Ensure that the affected superficial area is clean and dry.



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.
- StrataCTX should not be applied over topical medications unless advised by the physician.

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, burn creams 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. Moisturizers and burn creams may be applied after StrataCTX dries to maintain the first contact of StrataCTX with the skin. Unlike StrataCTX, moisturizers can cause irritation, and most burn creams are fully occlusive (means they do not allow gases to exchange through the skin). Adding any additional products over StrataCTX may reduce the effectiveness of StrataCTX.

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 for 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 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. StrataCTX does not require special disposal methods. Please follow your local disposal regulations.



StrataCTX - a non-steroidal gel for the management of inflammatory skin conditions and cutaneous reactions

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



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. Flohr, C., Hay, R. (2021). *Br J Dermatol*, 184, pp. 189-190. 2. Steele, CE. et al. (2019). *Current opinion in pediatrics*, 31(4), pp. 515-522. 3. American Academy of Dermatology Association. (2016). *Burden of Skin Disease, Skin disease briefs*. <https://www.aad.org/member/clinical-quality/clinical-care/bsd>. 4. Hunter, J. et al. (2002). *Clinical Dermatology*, 3rd edn. Malden, MA: Blackwell Science. 5. Mullings, J. et al. (2022). *Health-Related Quality of Life - Measurement Tools, Predictors and Modifiers*. London: IntechOpen. 6. Kelly, KA. et al. (2021). *Children*, 8(11), pp. 1057. 7. Carlos, G. et al. (2013). *Australian Prescriber*, 36, pp. 158-161. 8. Benedetto, AV. et al. (2021). *J Eur Acad Dermatol Venereol*, 35(1), pp. 247-255. 9. Szepletowski, J. (2014). *Nephrology Dialysis Transplantation*, 19(11), pp. 2709-2712. 10. Salava, A., Lauerma, A. (2014) *Clinical and Translational Allergy*, 4:33. 11. Nygaard, U. et al. (2013). *Case reports in dermatology*, 5(3), pp. 336-339. 12. StatPearls Publishing (2022). *NCBI Bookshelf. A service of the National Library of Medicine, National Institutes of Health*. <https://www.ncbi.nlm.nih.gov/books/NBK430879/>. 13. Lim D., Jibreal J. (2020). *Australasian College of Dermatologists*. <https://www.dermcoll.edu.au/atoz/erythema-annulare-centrifugum/>. 14. Dissemond, J. (2021). *Journal of the German Society of Dermatology (JDDG)*. <https://doi.org/10.1111/DDG.14388>. 15. Shergold, J., *Poster presented at Australian and New Zealand Children's Hematology/ Oncology Group (ANZCHOG) Annual Scientific Meeting*, Jun 15 -17, 2017, Adelaide, Australia. 16. Encyclopaedia: Blisters. NHS Direct Wales. <https://www.nhsdirect.wales.nhs.uk/encyclopaedia/b/article/blisters/>. Published 2019. Accessed July 1, 2019. 17. Perez-Soler, R. et al. (2005). *The oncologist*, 10(5), pp. 345-356. 18. Gomez, P., Lacouture, M. (2011). *The oncologist*, 16(11), pp. 1508-1519. 19. Inokuchi, M. et al. (2014). *Oncology Letters*, 7(2), pp. 444-448. 20. Riddell, S., Appelbaum, F. (2007). *PLoS Med*, 4(7), e198. 21. Cubiró Raventós X. et al. (2018). *SKINmed*, 17, pp. 298-304. 22. Marini, L. et al. (2017). *Dermatologic Surgery*, 43(1), pp. 85-90.