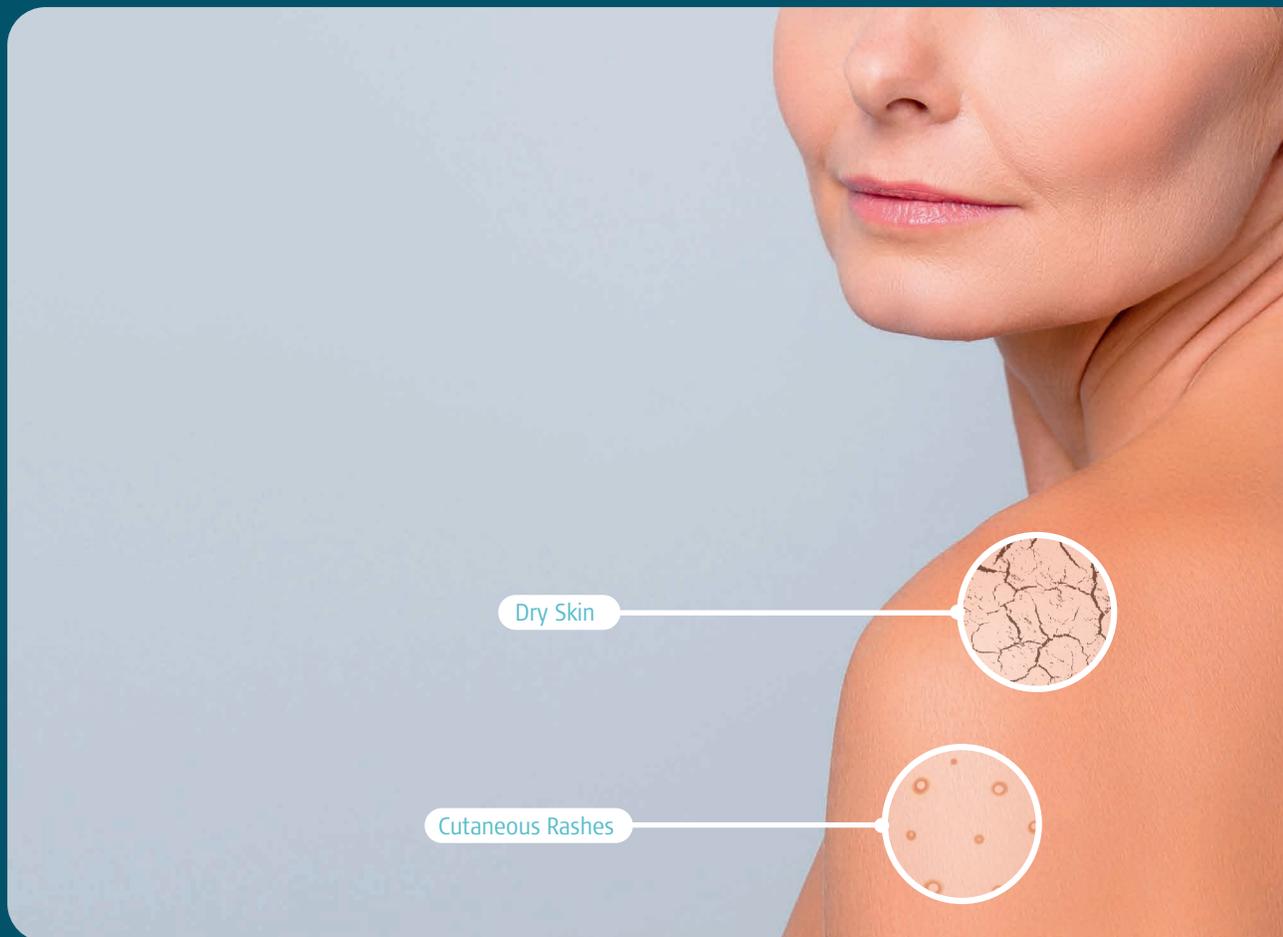


**Rx Only**  
For topical use only  
73661-421-50

ADVANCED FORMULATION  
**Strata cTx**<sup>®</sup>  
for cutaneous  
reactions

A non-steroidal, full contact,  
flexible wound dressing for the  
management of dry skin and  
cutaneous rashes



 **Stratapharma**  
Switzerland

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

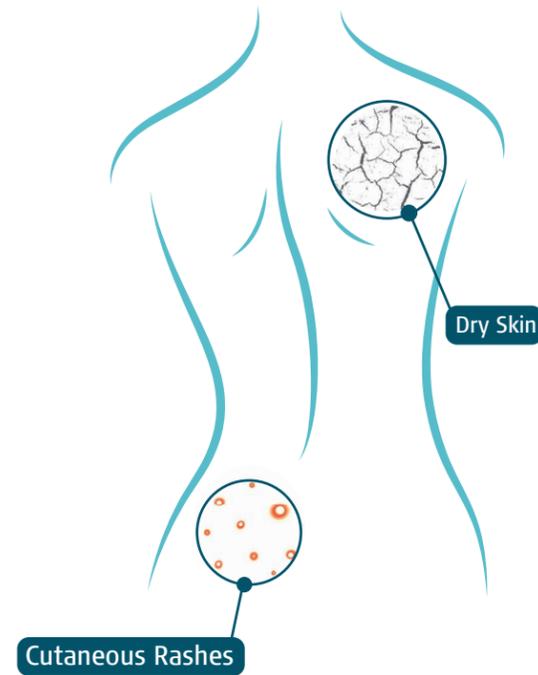
## Cutaneous reactions – etiology

Cutaneous reactions caused by targeted therapy, immunotherapy or Haematological treatments as well as medical adhesives are predictable and frequent skin conditions that 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**.<sup>1,2</sup>

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.<sup>3</sup>

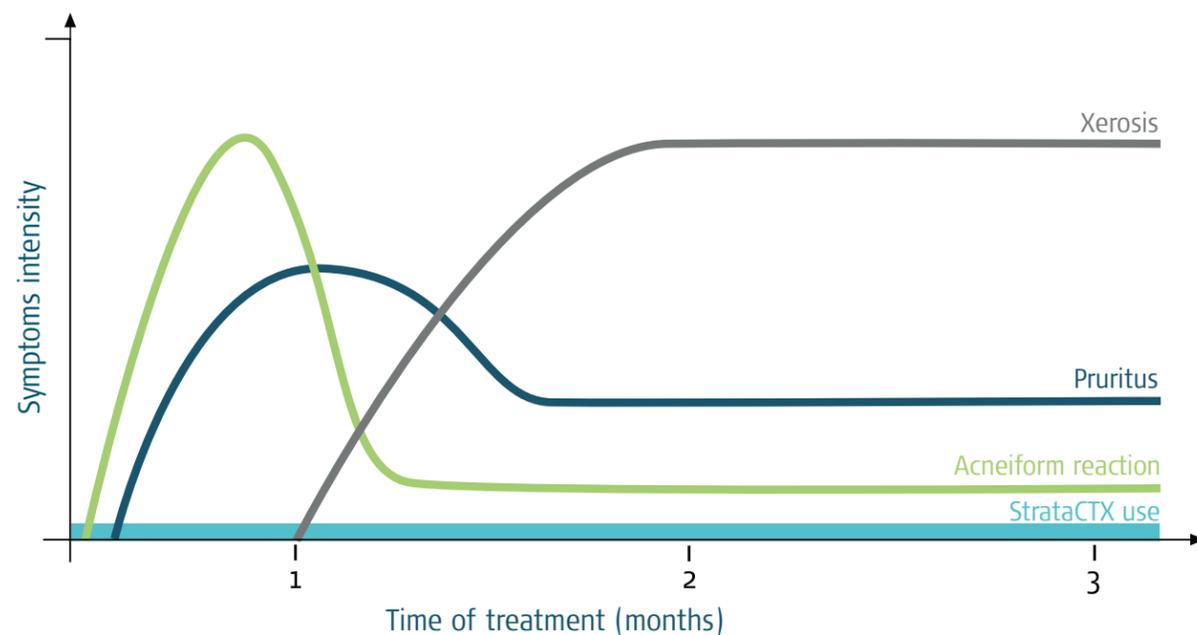
Early treatment of cutaneous reactions may prevent the exacerbation of symptoms, the need for reducing the medication dose, or the interruption of therapy.

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.<sup>2</sup>



## Progression of symptoms and cutaneous reactions<sup>4,5</sup>

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.

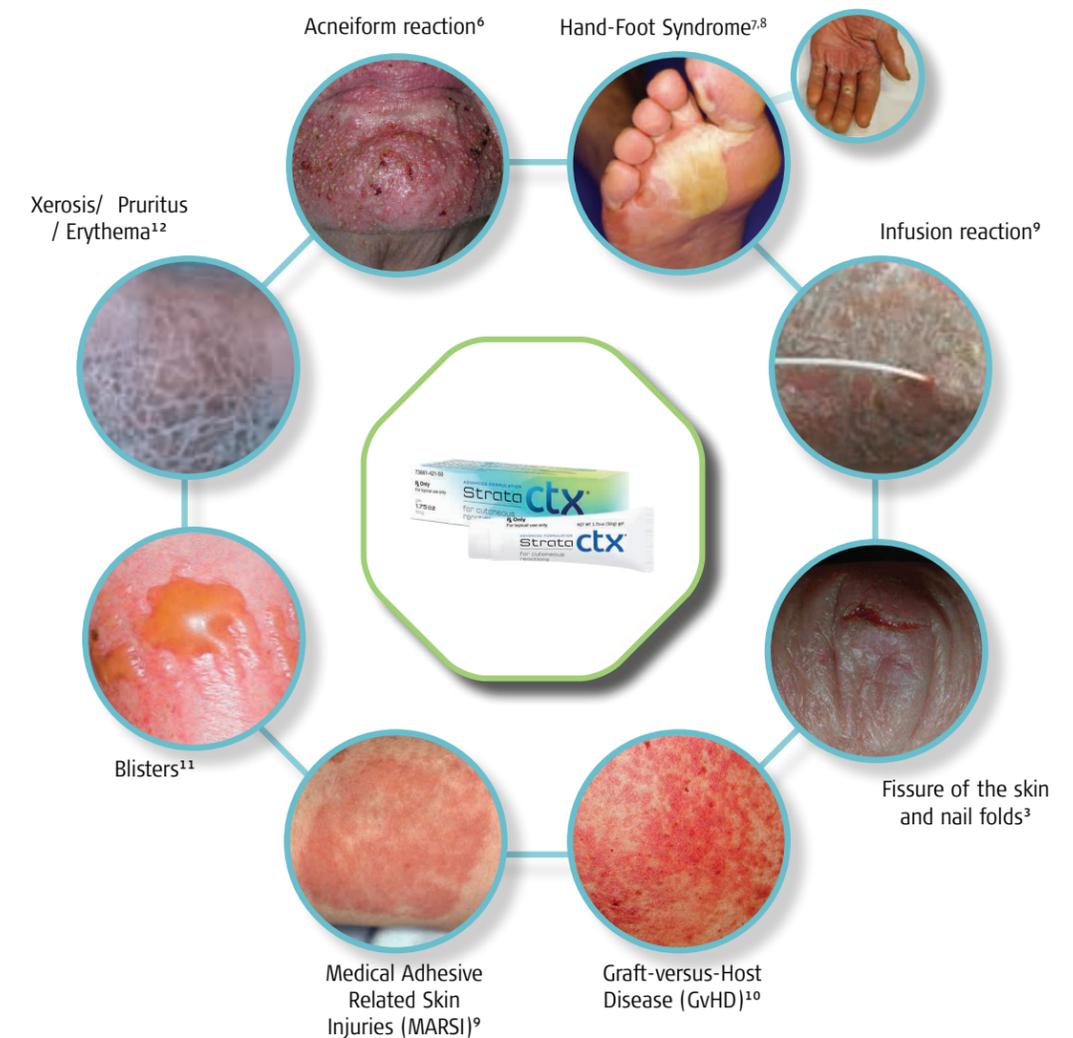


## StrataCTX indications

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 (MARSII)
- 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, FULL CONTACT, FLEXIBLE WOUND DRESSING

StrataCTX is a flexible, full contact wound dressing that forms a thin film that ensures 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 dries to form a protective layer that is gas permeable and waterproof which hydrates compromised skin areas and superficial wounds.



### 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, contains no steroids, alcohol, parabens or fragrances, making it suitable for children, and people with sensitive skin.



### 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.



### 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 convenient and easy to apply by patients at home.



## Clinical evidence with StrataCTX



Before treatment



After 5 days



Before treatment



After 14 days



Children's Health Queensland Hospital and Health Service, Australia

### Case series with 12 pediatric patients with Medical Adhesive-Related Skin Injuries (MARSI)<sup>9</sup>

- 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 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<sup>13</sup>

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

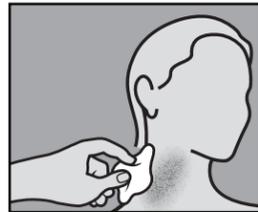
StrataCTX gel is an advanced formulation that requires substantially less gel per application than typical creams or gels.

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

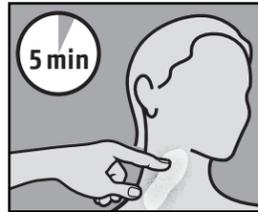
## How supplied

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

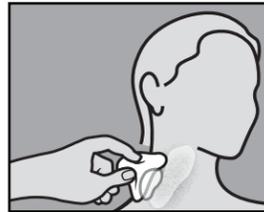
## Directions for use



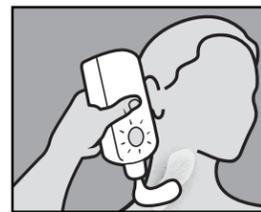
1. Ensure that the affected superficial area is clean and dry. Apply a very thin layer of StrataCTX directly to the affected area and allow the gel to dry.



2. When applied correctly to exposed areas, StrataCTX should be dry in 5-6 minutes. If it takes longer to dry you have probably applied too much.



3. 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 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 StrataCTX usage

- 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

## Filling a StrataCTX prescription

If StrataCTX will be picked up by the patient in an institutional pharmacy associated with your clinic, please share the tear sheet with the patient so they can receive the lowest co-pay possible.

Otherwise, StrataCTX can be filled by Truepill pharmacy. Please share the tear sheet with the patient and follow the instructions below.

Your patient will receive StrataCTX as you prescribed it with free delivery from Truepill pharmacy.

**Truepill**

We are processing your  
prescription. What's next?

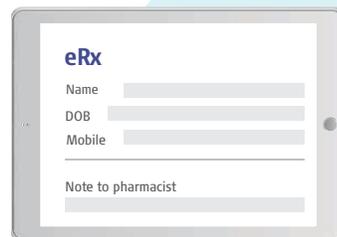
1

### Send script to Truepill

- eRx: Truepill (Hayward, CA) or NCPDP: 5660091
- Fax: 518-734-0053
- Verbal: 650-353-5495 | 855-910-8606

### To minimize callbacks, include:

- Patient's current mobile number
- Patient's email
- Patient insurance information
- Tried/failed meds or chart notes
- Allergies
- ICD-10 code



2

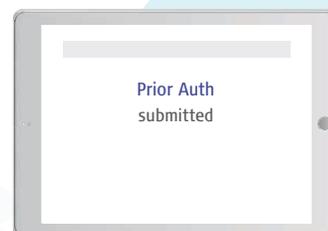
### Provide tear sheet to patient

Patient will receive a phone call or text with instructions on how to proceed with the prescription.

3

### Submit any prior auths in CoverMyMeds

with the key provided by Truepill. In the event CoverMyMeds does not process PA the pharmacy will notify you.



**Questions about prescription?** Contact Truepill's HCP support team at: 650-353-5495 | 855-910-8606 or [operations\\_support@truepill.com](mailto:operations_support@truepill.com)

[us.stratactx.com](http://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. Segaeert 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 Scientific 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 Sofia. Córdoba, Spain). Stratpharma AG.