#### R<sub>x</sub> Only

For topical use only 73661-421-50



# A non-steroidal gel for the management of inflammatory skin conditions and cutaneous reactions

Ideal for short- and long-term use







## What are inflammatory skin conditions?

**Inflammatory skin diseases** are frequently chronic skin conditions affecting millions of people worldwide and are the leading cause of global disease burden.<sup>1</sup>

22 million Americans sought medical treatment for **atopic**, **contact and seborrheic dermatitis**, **and psoriasis skin disorders**.<sup>2</sup>

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**.<sup>3,4</sup>

Children with inflammatory skin conditions are more likely to experience stigma, associated psychological conditions, and strained family relationships.<sup>5</sup>

To manage inflammatory skin diseases, it is vital to restore the barrier function of the skin and hydrate the affected area, while keeping the skin free from infection or environmental contamination.

## Some of the most common inflammatory skin conditions include:

**Eczema, or dermatitis,** is a common inflammatory skin condition which can affect anyone at any age.

Atopic dermatitis is one of the most common type of eczema, affecting up to 30% of children and persisting into adulthood in 25% of cases.<sup>6</sup>

Other types of eczema include contact and seborrheic dermatitis.

**Psoriasis** is a chronic inflammatory skin disorder, known to be the **most prevalent** autoimmune disease in humans. Up to 5% of the world's population suffers from psoriasis.<sup>7</sup>



**Chronic plaque** (psoriasis vulgaris) is the most common form of psoriasis, and accounts for about **90% of its** cases.<sup>8</sup>

### Treatment options

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

**Topical corticosteroids** may cause **local side effects** such as skin atrophy, increase in skin transparency and brightness, spider veins (telangiectasia), stretch marks, easy bruising, and **systemic side effects** of different severity.

The use of topical corticosteroids **on the face** can induce eruptions, such as red rashes around the mouth (perioral dermatitis), blushing or flushing (steroidal rosacea), and acne.<sup>9</sup>

There is a **growing concern** about contact dermatitis, delayed healing and antibiotic resistance due to **unrestricted use of topical antibiotics.**<sup>1,10</sup> **75**% of patients use over-the-counter petrolatum-based topical antibiotics **without doctor's prescription**, **and 21.6**% **of them develop contact dermatitis.**<sup>10</sup>

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

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

StrataCTX is non-reactive, it has no measurable pH, and contains no steroids, alcohol, parabens or fragrances, **allowing long-term use** and suitable for children and people with sensitive skin.

StrataCTX is bacteriostatic, **reducing the risk of infections** and **contact dermatitis** associated with topical antibiotics.

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



## 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:

## Inflammatory skin conditions and cutaneous reactions, including:

- Eczema, including: atopic, seborrheic and contact dermatitis
- Psoriasis
- · Dry, itching, flaking, peeling and irritated skin
- Ervthema (redness of the skin)
- Incontinence associated dermatitis and diaper rash
- Medical Adhesive-Related Skin Injuries (MARSI)

## Other medical indications, including upon administration of medications:

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

StrataCTX is designed to adhere gently to existing epidermis making it the **ideal product** for the management of cutaneous reactions and inflammatory skin conditions.

### Clinical evidence with StrataCTX

Pediatric patient with a dressing-related skin reaction (MARSI)<sup>11</sup>



Start of treatment with StrataCTX



After 5 days of treatment with StrataCTX



Children's Health Queensland Hospital and Health Service

#### Patient suffering from eczematous chelitis12



Start of treatment with StrataCTX



After 14 days of treatment with StrataCTX

Progressive **improvement of the skin** on a hard-to treat area due to StrataCTX's full contact film-forming, allowing the skin to breathe and remain hydrated.



#### 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 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.



#### **EASY TO USE**

StrataCTX is easy to apply by patients at home without the need for removal before re-application.

## 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 can be used with or without a secondary protective dressing.
- StrataCTX should not be applied over topical medications unless advised by your physician.
- 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, and skin lotions, 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 may be applied after StrataCTX dries to maintain the first contact of StrataCTX with the skin. Unlike StrataCTX, moisturizers can cause irritation, and some of them 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 topical corticosteroids and antibiotics.

### Dosage and administration

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



**StrataCTX 1.75 oz** (50 g) 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 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 inflammatory skin conditions and cutaneous reactions

#### StrataCTX:

- Significantly reduces the skin's inflammation reactions
- Reduces pain, redness and heat sensation
- Relieves dry, itching, flaking, peeling and irritated skin
- Promotes faster healing
- Hydrates and protects all types of compromised skin
- · Is bacteriostatic, reduces the risk of infection
- Is non-reactive, contains no alcohol, parabens or fragrances allowing long-term use for children and people with sensitive skin



#### Questions about Stratpharma products or prescriptions, 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: I. Flohr, C., Hay, R. (2021). Br. J Dermatol. 184, pp. 189-190. 2. American Academy of Dermatology Association
(2016). Burden of Skin Disease; Sach diseases briefs, https://lwww.aad.org/member/clinical-pullstylclinical-care/bsd 3. Hunter., et al. (2002). Clinical Dermatology. 3rd edn. Malden, MA: Blackwell Science. 4. Mullings, J. et al. (2022). Health-Related Quality of Life. Measurement Tools, Predictors and Modifiers. Londorn Interchopen S. Keyle, Ke. et al. (2021). Health-Related Quality of Life. Measurement Tools, Predictors and Modifiers. Sindorn Interchopen S. Keyle, Ke. et al. (2021). Health-Related Quality of Life. Steele, C. et al. (2019). Current opinion in pediatrics, 31(4), pp. 515-522. 7. Smitti RR. et al. (2014). Audinamunt/Reviews. 1314-51, pp. 409-495. 8. Boethocke, WH., Schon, MP (2015). Lancet, 386(9997), pp. 983-994. 9. Carlos, G. et al. (2013). Australian Preschep. 36, pp. 158-161. 10. Beenederlow Net et al. (2011). Fur Acad Demantol Nenerol, 31(1), pp. 247-255. 11. Shergold, J., Poster presented at Australian and New Zealand Children's Hematology Oncology Group (ANCCHOOL) Annual Scientiff Meeting, Jun 15-17, 2017, Adelaled, Australia. 12. Marini, L. et al. (2017). Demantologic Surgers, 43(1), pp. 857-96.

Manufactured by: Stratpharma AG Aeschenvorstadt 57, CH-4051 Basel, Switzerland Distributed by: Marnel Pharmaceuticals LLC Charleston, SC 29403, U.S.A. 1-833-788-0312



