CONTRAINDICATIONS

ELIDEL Cream, 1% is contraindicated in individuals with a history of hypersensitivity to tacrolimus or other silicone polymers. If you have a history of hypersensitivity to tacrolimus or other silicone polymers, use of ELIDEL Cream, 1% is not recommended.

ADVERSE REACTIONS

In clinical trials, the most common adverse reactions occurring in at least 1% of subjects treated with ELIDEL Cream, 1% were: application site pruritus, application site reaction, dermatitis, dry skin, local area reaction, burning, rash, and inflammation. Other common adverse reactions occurring in at least 1% but less than 10% of subjects treated with ELIDEL Cream, 1% were:

- Nervous System Disorders:
  - headache
  - dizziness
  - fatigue
  - anxiety
  - hyperesthesia
  - convulsion
  - paresthesia
  - tremor

- Ear Disorders:
  - earache

- Arthralgias

- Hypersensitivity NOS

- Conjunctivitis NEC

- Reproductive System and Breast Disorders:
  - insomnia
  - sexual dysfunction
  - gastroesophageal reflux disease

- Gastrointestinal Disorders:
  - diarrhea
  - constipation
  - nausea

- Genitourinary Disorders:
  - dysuria
  - urinary tract infection

- Respiratory, Thoracic, and Mediastinal Disorders:
  - dyspnea
  - pharyngitis
  - sinus congestion
  - nasal congestion

- Cutaneous Disorders:
  - pruritus
  - rash
  - erythema

- Other:
  - stinging
  - soreness

Continuous long-term use of ELIDEL Cream, 1% should be limited to individuals with atopic dermatitis who have been demonstrated to benefit from the use of a calcineurin inhibitor. The potential for superinfection (infected atopic dermatitis), rhinitis, and urticaria were found in the subjects treated with ELIDEL Cream, 1% alone. ELIDEL Cream, 1% should not be used in patients with Netherton's Syndrome or who have evidence of mycosis fungoides or CTCL, and those treated for any condition that may be independently associated with an increased risk of varicella zoster virus infection should be monitored for signs of such infections.

In cases where there is worsening of skin papillomas or they do not respond to conventional therapy, reevaluation with adequate biopsy should be undertaken. Epidermal cysts, particularly on the chest and back, may arise as part of the inflammatory process. While they are usually benign, diagnosis and treatment by appropriate surgical or nonsurgical means should be considered. If ELIDEL Cream, 1% is applied to an area with epidermal cysts, the cysts may rupture, and medical care should be sought.ELIDEL Cream, 1% should not be used in patients with Netherton's Syndrome or who have evidence of mycosis fungoides or CTCL, and those treated for any condition that may be independently associated with an increased risk of varicella zoster virus infection should be monitored for signs of such infections.

Nonserious cutaneous adverse events require medical attention if they are associated with signs or symptoms of infection or if they persist for more than 2 weeks. The potential for superinfection (infected atopic dermatitis), rhinitis, and urticaria were found in the subjects treated with ELIDEL Cream, 1% alone. ELIDEL Cream, 1% should not be used in patients with Netherton's Syndrome or who have evidence of mycosis fungoides or CTCL, and those treated for any condition that may be independently associated with an increased risk of varicella zoster virus infection should be monitored for signs of such infections.

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If ELIDEL Cream, 1% is used in combination with a topical corticosteroid, the corticosteroid dose should be reduced by 20%, if possible, to decrease the risk of superinfection. If ELIDEL Cream, 1% is used in a different strength, the local area reaction should be monitored. Localized symptoms are most common during the first 4 weeks of treatment. If they persist longer than 4 weeks, it is recommended that the product be discontinued. If ELIDEL Cream, 1% is used in a different strength, the local area reaction should be monitored. Localized symptoms are most common during the first 4 weeks of treatment. If they persist longer than 4 weeks, it is recommended that the product be discontinued.

Superinfection is a potential side effect of the use of topical calcineurin inhibitors. ELIDEL Cream, 1% may also be associated with increased risk of superinfection. The potential for superinfection (infected atopic dermatitis), rhinitis, and urticaria were found in the subjects treated with ELIDEL Cream, 1% alone. ELIDEL Cream, 1% should not be used in patients with Netherton's Syndrome or who have evidence of mycosis fungoides or CTCL, and those treated for any condition that may be independently associated with an increased risk of varicella zoster virus infection should be monitored for signs of such infections.

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For the duration of therapy, patients presenting with nasopharyngitis, respiratory symptoms, or other signs of respiratory infection should be closely monitored for early signs of infection. Appropriate treatment should be administered. If symptoms persist or worsen, treatment should be discontinued. All patients should continue to receive the usual precautions associated with the use of steroids, e.g., regular check-ups with their physician and treatment of infections promptly.

Infectious diseases can be more severe in patients receiving immunosuppressive therapy. Both infectious mononucleosis and varicella infections in orifices and severe varicella infection in children have been reported in immunocompromised patients. In some individuals, the condition may become more severe with the use of systemic and local corticosteroids. In patients who have bacterial infections, corticosteroids may mask the symptoms of the infection, and inhibit their diagnosis. In patients who have viral infections, corticosteroids may delay the diagnosis and treatment of the infection. In patients with fungal infections, corticosteroids may delay the diagnosis and treatment of the infection. In patients with parasitic infections, corticosteroids may delay the diagnosis and treatment of the infection.