

## Topical calcineurin inhibitors

### Key Questions and Inclusion Criteria

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1. For adults and children with stable atopic dermatitis or eczema, do pimecrolimus or tacrolimus differ in effectiveness when compared to each other and when compared to topical corticosteroids:
  - a. depending on location of application (e.g., head and neck, flexures, hands, feet, intertriginous regions)?
  - b. depending on body surface area involved?
  - c. depending on treatment duration?
2. For adults and children with stable atopic dermatitis or eczema, do pimecrolimus or tacrolimus differ in safety or adverse events when compared to each other and when compared to topical corticosteroids:
  - a. depending on location of application (e.g., head and neck, flexures, hands, feet, intertriginous regions)?
  - b. depending on body surface area involved?
  - c. depending on treatment duration?
3. Are there other subgroups of patients based on demographics (e.g., age, racial groups, gender) and comorbidities (e.g., immunodeficiencies) for which either pimecrolimus or tacrolimus is more effective or associated with fewer adverse events?

#### Inclusion Criteria

##### Population(s)

- Adults and children with stable atopic dermatitis or eczema

##### Interventions

- Pimecrolimus (Elidel®)
- Tacrolimus (Protopic®)

##### Indirect comparators

- Placebo
- Topical corticosteroids

##### Effectiveness outcomes

- Frequency of rebound flare-ups
- Reduction in symptom severity (e.g., sleep loss, pruritus, etc)
- Duration of effectiveness (e.g., time to next flare-up)
- Quality of Life
- Treatment failure (e.g., use of alternative treatments)

Safety outcomes

- Overall adverse effects reported
- Withdrawals
- Withdrawals due to adverse effects
- General adverse events (e.g., burning, stinging)
- Major adverse events (e.g., cancers, infections, glaucoma, sensitivity to temperature changes, cutaneous atrophy)

Study designs

- For effectiveness, randomized controlled trials with duration of  $\geq 3$  weeks and good-quality systematic reviews
- For safety, randomized controlled trials with duration of  $\geq 3$  weeks, good-quality systematic reviews, and observational studies (cohort including database studies with comparison group, case-control, before-after studies) with duration of study  $\geq 3$  weeks
  - Case reports, case series, and single-arm extension studies excluded