

## Vectical® (calcitriol) – Expanded indication

- On July 17, 2020, the <u>FDA approved</u> Galderma's <u>Vectical (calcitriol)</u>, for the topical treatment of mild to moderate plaque psoriasis in adults and pediatric patients 2 years and older.
  - Vectical was previously approved for this indication in adults 18 years and older.
  - The safety and effectiveness of Vectical in patients with known or suspected disorders of calcium metabolism have not been evaluated.
- The use of Vectical in pediatric patients is supported by two adequate and well-controlled 8-week trials and an open label trial in adult patients, and additional data from trials conducted in pediatric patients 2 to 17 years of age.
  - Data from 63 patients ages 2 to 12 years, and 42 patients ages 13 to 17 years showed no significant effects on indices of calcium metabolism.
  - The systemic exposure of calcitriol in the pediatric patients was generally comparable to the endogenous levels observed at baseline. No new safety signals were identified in subjects 2 to 17 years.
- The recommended administration of Vectical ointment for the treatment of pediatric patients is an
  application to affected areas twice daily (morning and evening). In pediatric patients 2 to 6 years of
  age, the maximum weekly dose should not exceed 100 grams. In pediatric patients 7 years of age
  and older, the maximum weekly dose should not exceed 200 grams.
  - Refer to the Vectical drug label for dosing recommendations in adults.



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