Vectical® (calcitriol) – Expanded indication

- On July 17, 2020, the FDA approved Galderma’s Vectical (calcitriol), 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.