Taclonex® (calcipotriene/betamethasone dipropionate) – Expanded indication

- On July 31, 2019, Leo Pharma announced the FDA approval of Taclonex (calcipotriene/betamethasone dipropionate) topical suspension, for the topical treatment of plaque psoriasis of the scalp and body in patients 12 years and older.
    - Previously, Taclonex was approved for the topical treatment of plaque psoriasis of the scalp in patients 12 years and older, and for plaque psoriasis of the body in patients 18 years and older.
- Taclonex is also available generically as an ointment.
    - The generic ointment is approved for the topical treatment of plaque psoriasis in patients 18 years of age and older.
    - The branded Taclonex ointment is approved for the topical treatment of plaque psoriasis in patients 12 years of age and older.
- The safety and effectiveness of Taclonex for the treatment of plaque psoriasis of the scalp and body have been established in pediatric patients age 12 to 17 years.
    - The use of Taclonex for this indication is supported by evidence from adequate and well-controlled trials in adults and from three uncontrolled trials in pediatric subjects that enrolled 109 adolescents with moderate psoriasis of the scalp and 107 adolescents with psoriasis of the scalp and body.
- The recommended dosage regimen for patients 12 years of age and older is to apply Taclonex to affected areas on the scalp and body once daily for up to 8 weeks. Taclonex should be discontinued when control is achieved.
    - Patients 12 to 17 years should not use more than 60 grams per week and patients 18 years and older should not use more than 100 grams per week.
    - Refer to the Taclonex dosing label for additional administration recommendations.