Sorilux® (calcipotriene) – Expanded indication

- On May 6, 2019, the FDA approved Mayne Pharma's Sorilux (calcipotriene) foam, for the topical treatment of plaque psoriasis of the scalp and body in patients 12 years and older.
    - Sorilux was previously approved for this indication in patients 18 years and older only.
- The effectiveness of Sorilux in pediatric patients age 12 years and older was supported by two adequate and well controlled 8-week trials in adults and adolescents 12 years of age and older, with additional data from a 15-day open-label safety and pharmacokinetics study conducted in 19 patients 12 to less than 17 years of age with psoriasis.
    - Data from 17 patients in the pharmacokinetic study showed no significant effects on indices of calcium metabolism and no quantifiable calcipotriene concentrations in patients aged 12 to less than 17 years.
- The recommended dosage and administration for Sorilux is an application of a thin layer twice daily to the affected areas.
- Sorilux is for topical use only. Sorilux is not for oral, ophthalmic, or intravaginal use.