

Sorilux[®] (calcipotriene) – Expanded indication

- On November 5, 2019, the <u>FDA approved</u> Mayne Pharma's <u>Sorilux (calcipotriene)</u> foam, for the topical treatment of plaque psoriasis of the scalp and body in adults and pediatric patients 4 years of age and older.
 - Sorilux was previously approved for this indication in patients 12 years and older.
- The use of Sorilux in pediatric patients age 4 years and older is 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 (PK) study conducted in 19 subjects 12 to less than 17 years of age; and an 8-week open-label safety and PK study in 36 subjects 4 to 11 years of age with psoriasis.
- The recommended administration of Sorilux foam in all patients is an application of a thin layer twice daily to the affected areas.



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