



## Natroba® (spinosad) – New indication

- On April 28, 2021, the [FDA approved](#) ParaPRO's [Natroba \(spinosad\)](#), for the topical treatment of scabies infestations in adult and pediatric patients 4 years of age and older.
  - Adjunctive measures for scabies infestations include washing in hot water or dry-clean any bedding, clothing and towels used by anyone having scabies.
- Natroba is also approved for the topical treatment of head lice infestations in adult and pediatric patients 6 months of age and older.
- The approval of Natroba for the new indication was based on two randomized, double-blind, vehicle-controlled studies in 533 adult and pediatric patients from 206 households in which at least one household member 4 years of age or older had an active scabies infestation. All members of the household were treated with the same randomized treatment (Natroba or vehicle), whether or not the household member had an active scabies infestation. For the evaluation of efficacy, the youngest patient from each household with an active scabies infestation was considered to be the primary subject of the household. Efficacy was assessed as the proportion of primary patients who achieved complete cure 28 days after treatment.
  - In study 1, complete cure was achieved in 69.8% and 46.5% of patients with Natroba and vehicle, respectively (estimated difference: 22.7, 95% CI: 1.8, 43.5).
  - In study 2, complete cure was achieved in 83.9% and 34.5% of patients with Natroba and vehicle, respectively (estimated difference: 49.7, 95% CI: 36.0, 63.5).
- For the treatment of scabies infestations, a sufficient amount of Natroba should be applied to skin to completely cover the body from the neck to the toes (including the soles of the feet). For patients with balding scalp, product should also be applied to the scalp, hairline, temples, and forehead.
  - Refer to the Natroba drug label for complete administration recommendations for scabies and head lice infestations.



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