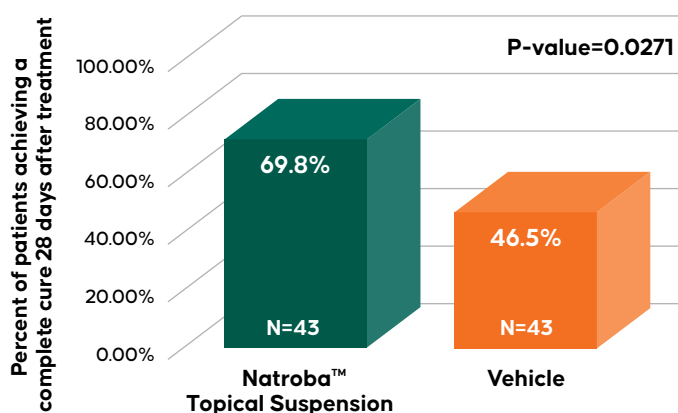


Natroba™ demonstrates the first “complete cure” for scabies.⁴

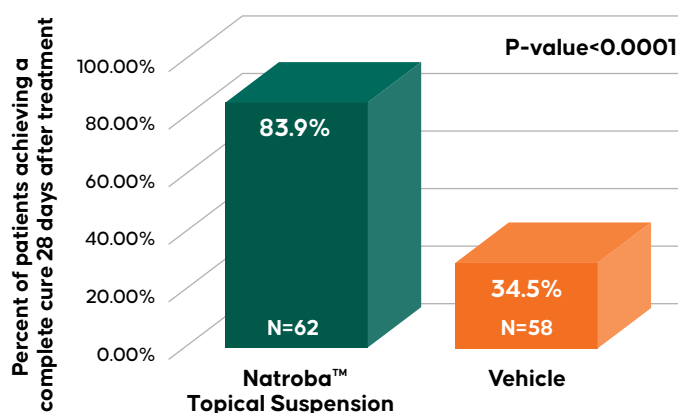
Despite scabies’ prevalence and burden on public health, physicians have relied on treatments dating back to 1989 and earlier^{1,2} to help patients overcome this “neglected, intensely pruritic”, ectoparasitic, skin infestation. But none of those pharmacologic options meet today’s FDA criteria for a “complete cure” of scabies³...until now.

Targeted topical Natroba™ (spinosad) therapy offers substantiated, “complete cure” efficacy outcomes in treating adult and pediatric (4 years of age and older) scabies infestations.⁴

Study 1: Complete Cure Outcomes



Study 2: Complete Cure Outcomes



In two phase 3, multicenter, randomized, double-blind, vehicle-controlled studies, under patient-directed usage, evaluating a single application of Natroba™ or vehicle in 206 patients, significantly more patients using Natroba™ achieved a complete cure 28 days after treatment compared to vehicle, 69.8% vs. 46.5% (P-value=0.0271) and 83.9% vs. 34.5% (P-value<0.0001), respectively. Patients were less likely to develop new scabies lesions over the 28 days following treatment with Natroba™ than following treatment with vehicle.⁴

References: 1. U.S. FDA. (2018). Summary of NDA Approvals & Receipts, 1938 to the present. Retrieved from <https://www.fda.gov/about-fda/histories-product-regulation/summary-nda-approvals-receipts-1938-present>. 2. LaMattina, J. (2019). Can The Record Breaking Number Of FDA New Drug Approvals Continue? Forbes. Retrieved from <https://www.forbes.com/sites/johnlamattina/2019/01/09/can-the-record-breaking-number-of-fda-new-drug-approvals-continue/?sh=260bdf15aa831>. 3. ParaPRO, LLC & Concentrics Research (2018). A Phase 3, Randomized, Double Blind, Placebo-Controlled Study to Assess the Safety, Efficacy and Pharmacokinetics of Natroba™ (spinosad) for the Treatment of Scabies (Clinical Study Protocol, Amd. 6.0, pp. 1-66). 4. Natroba Prescribing Information.

INDICATION

Natroba™ Topical Suspension is a scabicide indicated for the topical treatment of scabies infestations in adult and pediatric patients four (4) years of age and older.

ADJUNCTIVE MEASURES

- Wash in hot water or dry-clean any bedding, clothing and towels used by anyone having scabies.
- If any member of a household presents with scabies, all household members should be treated with Natroba™ Topical Suspension.

IMPORTANT SAFETY INFORMATION

Natroba™ Topical Suspension contains benzyl alcohol and is not recommended for use in pediatric patients below the age of 4 years. The safety and effectiveness of Natroba™ Topical Suspension have not been established in pediatric patients less than 4 years of age with scabies infestation. Most common adverse events were: application site irritation (3%)* and dry skin (2%).

*Application site irritation also includes application site pain and burning sensation.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.