



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Natroba™

Common Name: spinosad

PDL Category: Topical- Scabicides and Pediculicides

| <u>Comparable Products</u> | <u>Preferred Drug List Status</u> |
|-------------------------------|-----------------------------------|
| Ovide® | Non-Preferred |
| Permethrin | Preferred |
| Pyrethrins-Piperonyl Butoxide | Preferred |

Summary

Indications and Usage: Topical treatment of head lice infestations in patients 4 years of age and older. ¹

Mechanism of Action: Causes neuronal excitation in insects. After periods of hyperexcitation, lice become paralyzed and die. ¹

Dosage Forms: Topical Suspension; 0.9% ¹

Recommended Dosage: Apply to dry scalp and hair using only enough needed to cover the scalp and hair. Rinse off with warm water after 10 minutes. Repeat treatment if live lice are seen 7 days after initial treatment. ¹

Common Adverse Drug Reactions: Application site erythema and ocular erythema. ¹

Contraindications: None ¹

Manufacturer: ParaPRO LLC

Analysis: Natroba™ is a new topical agent indicated for the treatment of head lice infestations in patients 4 years of age and older. Natroba™ contains benzyl alcohol, which is not recommended for use in neonates or infants <6 months of age as systemic exposure may cause serious adverse events and even death. There were two randomized, investigator-blinded, active-controlled studies performed to establish the safety and efficacy of spinosad for treatment of lice. In study 1, 91 subjects aged 6 months or older with active head lice were treated with Natroba® and 89 were treated with permethrin, the active comparator. In study 2, 83 subjects were treated with Natroba® and 84 with permethrin. The primary efficacy was those who were free of live lice 14 days after the final treatment. In study 1, 84.6% of the Natroba® treated group was free of live lice 14 days after treatment vs 44.9% with those treated with permethrin. In study 2, 86.7% of the Natroba® treated group was free of live lice 14 days after treatment vs 42.9% of the permethrin group. Although clinical trials demonstrate there are greater effects seen with Natroba™ compared to permethrin, there is no evidence to support Natroba™ is more efficacious than all other medications currently available for the treatment of head lice. Preferred alternatives are available on the PDL that are more cost effective. It is recommended that Natroba™ be added to the Preferred Drug List as a non-preferred drug.

IME Recommendation: Preferred Drug Recommended Drug
 Non-Preferred Drug Non-Recommended Drug
 Non-Preferred Drug with Conditions Refer to DUR for PA criteria

1. Natroba™ [package insert]. Carmel, IN: ParaPRO LLC; 2011.