



## Xeglyze™ (abametapir) – New drug approval

- On July 24, 2020, the FDA approved Dr. Reddy's Laboratories' Xeglyze (abametapir), for the topical treatment of head lice infestation in patients 6 months of age and older. Xeglyze should be used in the context of an overall lice management program:
  - Wash (with hot water) or dry-clean all recently worn clothing, hats, used bedding and towels
  - Wash personal care items such as combs, brushes, and hair clips in hot water
  - A fine-tooth comb or special nit comb should be used to remove dead lice and nits.
- Xeglyze is a metalloproteinase inhibitor. Metalloproteinases have a role in physiological processes critical to egg development and survival of lice.
- The efficacy of Xeglyze was established in two identical, randomized, double-blind, vehicle-controlled trials in 704 patients 6 months of age and older with head lice infestation. All patients received a single application of either Xeglyze or vehicle control. For the evaluation of efficacy, the youngest patient from each household was considered to be the index patient of the household (n = 216). Other enrolled infested household members received the same treatment as the youngest subject and were evaluated for all efficacy and safety parameters. Efficacy was assessed as the proportion of index patients who were free of live lice at all follow-up visits on days 1, 7, and 14.
  - In study 1, the proportion of index patients free of live lice at all visits was 81.1% with Xeglyze vs. 50.9% with vehicle.
  - In study 2, the proportion of index patients free of live lice at all visits was 81.8% with Xeglyze vs. 47.2% with vehicle.
- Warnings and precautions for Xeglyze include risk of neonatal benzyl alcohol toxicity and risk of benzyl alcohol toxicity from accidental ingestion.
- The most common adverse reactions ( $\geq 1\%$ ) with Xeglyze use were erythema, rash, skin burning sensation, contact dermatitis, vomiting, eye irritation, pruritus, and hair color changes.
- Treatment with Xeglyze involves a single application. Xeglyze should be applied to dry hair in an amount (up to the full content of one bottle) sufficient to thoroughly coat the hair and scalp. It should be left on the hair and scalp for 10 minutes and then rinsed off with warm water.
- Dr. Reddy's Laboratories' launch plans for Xeglyze are pending. Xeglyze will be available as a 0.74% lotion.



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