



### Tolak™ (fluorouracil) – New Drug Approval

- On September 18, 2015, the [FDA approved](#) Hill Dermaceuticals' [Tolak \(fluorouracil\)](#) for the topical treatment of actinic keratosis (AK) lesions of the face, ears, and/or scalp.
- AK is a scaly, crusty lesion on the skin that may be red or yellow in color. The lesions are typically located on areas exposed to the sun (eg, face, scalp, chest). The majority of these lesions are not harmful. However, AK may occasionally develop into skin cancer.
  - Over [58 million](#) Americans are estimated to have AK.
- Tolak contains fluorouracil, a nucleoside metabolic inhibitor. Fluorouracil interferes with DNA synthesis and to a lesser extent with the formation of RNA, which affect cells that grow rapidly.
- The safety and efficacy of Tolak were based on results from two double-blind, placebo-controlled trials in subjects with  $\geq 5$  visible AK lesions. The effect of treatment was assessed at 4 weeks post-treatment.
  - The percentage of patients with 100% clearing of AK lesions was 54% and 4% (Trial 1) and 24% and 4% (Trial 2) in the Tolak vs. placebo groups, respectively.
  - The percentage of patients with 75% clearing of AK lesions was 80% and 7% (Trial 1) and 74% and 10% (Trial 2) in the Tolak vs. placebo groups, respectively.
- Tolak is contraindicated in pregnancy and in patients with dihydropyrimidine dehydrogenase (DPD) deficiency.
- Warnings and precautions of Tolak include application site adverse reactions, hypersensitivity reactions, ophthalmic adverse reactions, photosensitivity, and embryofetal toxicity.
- The most common adverse reactions (> 68%) with Tolak use occur at the application site and include erythema (99%), scaling/dryness, crusting, pruritus, stinging/burning, edema, and erosions.
- Tolak should be applied topically once daily in an amount sufficient to cover the lesions of the face, ears, and/or scalp with a thin film for a period of 4 weeks as tolerated.
  - Tolak is for external use only and should not be applied to eyes, nose, mouth, or mucous membranes.
- Hill Dermaceuticals plans to launch Tolak by the end of October 2015. Tolak will contain 40 mg of fluorouracil per gram of cream (4%) in a 40 gram tube.



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