

Supplemental Approvals

Generic Name (Trade Name—Company)

July 18, 2011

Uses/Notes

Treatment of actinic keratosis on the face or balding scalp

Imiquimod

(Zyclara—Graceway)

New strength approved

[Graceway](#) announced the FDA approval of a new strength of its imiquimod cream, 2.5%, for the treatment of actinic keratosis on the face or balding scalp. The cream is currently available in a 3.75% strength for the treatment of actinic keratosis and genital warts. Data were collected in four double-blind studies comparing the 2.5% and 3.75% creams versus placebo. Patients applied imiquimod 2.5% on a 2 weeks on, 2 weeks off, 2 weeks on dosing cycle, and results showed that patients in the 2.5% treatment group experienced fewer local skin reactions than with the higher strength formulation. In addition, 31% of patients using imiquimod 2.5% cream had complete clearance of actinic keratosis, compared with 6% of patients in the placebo group.

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