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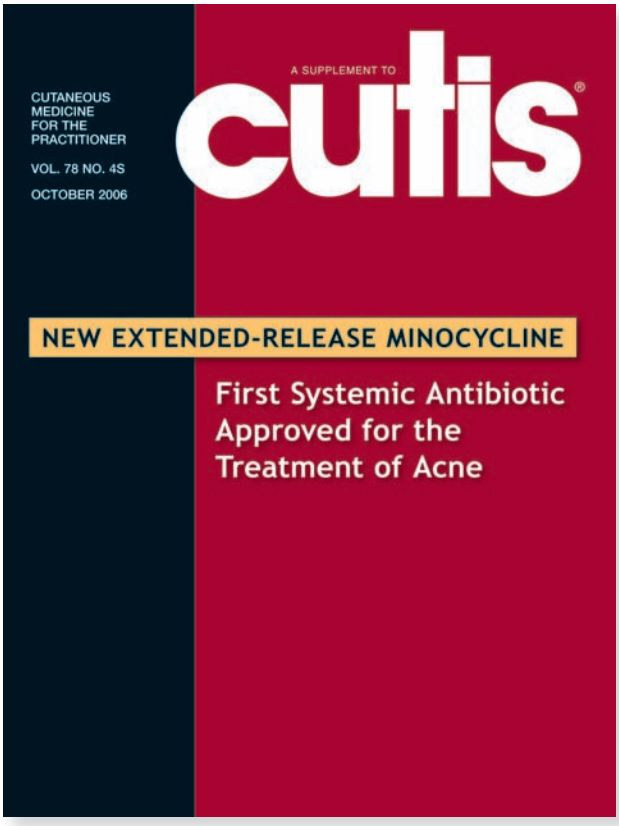

New Extended-Release Minocycline: First Systemic Antibiotic Approved for the Treatment of Acne

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For a long time, minocycline has been recognized as highly efficacious for the treatment of acne vulgaris but with use-limiting acute vestibular adverse events (AVAEs). Based on the concept that lowered overall systemic exposure to minocycline should reduce unwanted side effects, a program was initiated to develop a modified-release formulation for clinical testing. An extended-release (ER) minocycline hydrochloride tablet formulation was developed that demonstrated delayed time of maximum concentration (t_{max}, 3½–4 hours) compared with a nonmodified-release minocycline (t_{max}, 2¼–3 hours), and a lower maximum concentration of drug (c_{max}) in the blood (90%) compared with nonmodified-release formulations. At steady state (day 6), the ER-minocycline formulation had a 0- to 24-hour area under the curve (AUC_{0-24}) and c_{max} of 33.32 µg×h/mL and 2.63 µg/mL, respectively, compared with

46.35 µg×h/mL and 2.92 µg/mL, respectively, for the nonmodified-release minocycline. These studies demonstrated that the new ER–minocycline hydrochloride formulation is not bioequivalent to the immediate-release (IR) minocycline hydrochloride formulation currently on the market. The favorable pharmacokinetic profile of ER minocycline also was not affected by concomitantly ingested food, including dairy products.