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Prulifloxacin

A Viewpoint by Claudio Giberti

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Prulifloxacin, the prodrug of ulifloxacin, is a new oral fluoroquinolone that is taken once daily. It is indicated in the treatment of simple cystitis, complicated urinary tract infections (UTIs), and acute exacerbation of chronic bronchitis (AECB).

Dose-finding ciprofloxacin-controlled clinical trials performed in patients with the above indications showed that, compared to other prulifloxacin dosages (300mg once daily, 450mg once daily and 300mg twice daily), the 600mg once daily dosage was the most effective, supported by a good safety and tolerability profile.

In phase III controlled clinical trials performed in accordance with criteria suggested by the International Guidelines for the assessment of anti-infective drug products, prulifloxacin efficacy rates were 84.6% and 94.2% in patients with AECB, and ranged from 90% to 98% in patients with UTIs.

The proven therapeutic equivalence of prulifloxacin 600mg once daily with ciprofloxacin 500mg twice daily, single-dose pefloxacin 800mg and amoxicillin/clavulanic acid 1g twice daily, allows the clinician to consider prulifloxacin an important addition to the drug armamentarium, especially when a broad-spectrum antibacterial agent, administered as a single daily dose and likely to improve patient compliance, is required.

The tolerability profile of the drug seen in the clinical trials performed in Europe is at least comparable with that of ciprofloxacin and probably better than that of amoxicillin/clavulanic acid. The negligible concentration of ulifloxacin observed in animal CNS tissues may represent a low potential for the CNS adverse reactions (e.g. insomnia) that are frequently observed in patients treated with quinolones.

The high concentrations of ulifloxacin detected in urine up to 48 hours after administration and its activity against Gram-negative bacteria, together with the consistent tolerability profile, suggest that prulifloxacin is safe and effective when used in the treatment of UTIs. ▲