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Butenafine

A Viewpoint by Gérald Piérard

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A handful of *in vitro* studies has suggested a fungicidal activity of the benzylamine butenafine HCl against a series of dermatophytes. Yeasts appeared little affected by the drug. As for other antifungals, such *in vitro* data must be interpreted with caution because there is great variation in the minimum inhibitory concentrations and minimum lethal concentrations according to the fungal strains and to laboratory procedures for the *in vitro* testing. Discrepancies and controversies are rife in this field. As a result, it is generally acknowledged that *in vitro* methods remain unreliable for predicting *in vivo* outcomes and directing therapy.

Studies were conducted on guinea-pigs by Arika and coworkers to further establish the antifungal efficacy of butenafine HCl. They indicated good prophylactic and therapeutic effects of the drug in experimental dermatophytosis.

The clinical efficacy and safety of butenafine HCl cream 1% was also evaluated in humans. Some trials did not use a vehicle control, and did not require a culture after the baseline visit as the criterion of mycological cure and/or did not assess efficacy after the cessation of therapy. Results were quoted as excellent in about 40 to 65% of the patients and were similar to those of bifonazole or clotrimazole. Other well controlled studies supported the good safety profile of the topical formulation. They also showed that the drug was superior in efficacy to its vehicle after a 2- to 4-week treatment period and that the drug-related improvement was even greater at the 4-week follow-up.

In summary, butenafine HCl shows a promising profile as a topical antifungal drug. The overall activity compares with some reference azole formulations. The post-treatment efficacy of butenafine suggests that the drug has potential to reduce the risk of relapse or recurrence after premature discontinuation of therapy. ▲