

## Current and future investigations

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Betamethasone valerate (BMV) is a potent glucocorticoid, firstly approved for marketing in 1967 for the treatment of severe inflammatory skin disorders such as eczemas unresponsive to less potent corticosteroids, psoriasis, lichenifications and other recalcitrant dermatoses.

In addition to the “classical” cream, ointment and lotion formulations, usually all at a strength of 0.1% BM base, BMV is now available as a waterproof, self-adhesive medicated plaster. The product has recently received the marketing authorisation approval by the Italian Agency with the trademark *Betesil*<sup>®</sup> *2,250 mg medicated plaster*.

Substantial advantages over marketed creams/ointments of this ready-to-use, fix-dose form would be the reduction of the risk of inappropriate or incorrect administration, a uniform distribution of BMV limited to the affected skin area (by avoiding the occasional diffusion of product on to unaffected areas), a protection from local trauma (e.g. elbow or knee) and irritation (e.g. scratching), two important pathogenetic factors that can worsen the disease and delay healing and, last but not least, an enhanced patient’s compliance - a major problem when prescribing a topical treatment – by avoiding the typical stains on clothes and the greasy skin sensation.

Overall, all safety and efficacy important aspects have been investigated to date by means of clinical trials using widely accepted and validated methods, in well controlled and highly standardised protocols. Nonetheless, the willingness of the Sponsor to confirm the efficacy and the therapeutic value of the new BMV occlusive formulation brought us to set up a new clinical trial, using an experimental design as near as possible to the daily clinical practice setting and also reflecting the most recent requirements as contained in the EU guideline on clinical investigation of medicinal products indicated for the treatment of psoriasis (CHMP/EWP/2454/02corr), enforced in June 2005.

The various methodological aspects of the ongoing European multicentre, prospective, assessor-blind, confirmatory trial are presented, together with the main topics of clinical protocols currently under development.

