

Evaluation of specific clinical safety aspects of the new BMV medicated plaster formulation

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Corticosteroids are the most widely used topical treatment for chronic psoriasis. Corticosteroids have well-recognized antiinflammatory, antiproliferative and immunosuppressive properties; they inhibit dermal edema, capillary dilatation and migration of inflammatory cells through the skin. In addition, corticosteroids inhibit immune function and cellular proliferation in the dermis and epidermis.

Betesil medicated plaster is a transparent adhesive tape containing betamethasone 17-valerate as active ingredient ($=0.03\text{mg}/\text{cm}^2$). The concentration of the corticosteroid in the adhesive layer is 0.1%. Topical formulations containing 0.12% betamethasone valerate are classified within the potent topical corticosteroids group according to the European Classification.

Occlusion is a widely accepted procedure to enhance the efficacy of topical corticosteroids, especially in the treatment of psoriasis. However, use of plastic film dressings may create its own problems, such as unsightly appearance, poor adhesion, maceration of tissue, induction of microbial overgrowth and increase local adverse effects such as skin atrophy and telangiectasia. Moreover, occlusion can enhance the penetration of the drug with a higher concentration at the target site but also can result in higher concentration at the systemic level.

The local and general safety of Betesil medicated plaster was to be assessed to demonstrate that the plaster has more advantages than conventional occlusive dressings with no more side effects.

In our centre, the potentials for atrophogenicity and for HPA axis suppression of Betesil medicated plaster were separately investigated by means of appropriate, validated methodology both in healthy volunteers and psoriatic patients.

