

# BETAMETHASONE VALERATE MEDICATED PLASTER (BMVP) 2.250 mg (BETESIL®) PRODUCT REVIEW

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## Introduction

Managing chronic inflammatory skin conditions is the mainstay of our work in dermatology. Inflammatory skin conditions such as psoriasis and eczema are so very common with many different clinical presentations. Not all persons with a skin condition are eligible for systemic treatments and therefore the fundamentals of management continue to be appropriate *topical* corticosteroid therapies which remain a therapeutic class for inflammatory dermatological conditions.<sup>1</sup>

The art and the science of management becomes evident when we, as health professionals, consider what topical treatments are available for specific conditions and presentations. For example, the topical management one considers for guttate psoriasis may differ to that considered for chronic large plaque psoriasis or localised plantopustular psoriasis. Similarly, within the 'eczema' range, the topical treatments suggested for atopic eczema can differ considerably to that of nummular eczema, or seborrheic eczema. In addition, inflammatory skin lesions in difficult to treat areas always represent a clinical challenge for both health professional and patient.

This article is a product review of a well-known potent topical

corticosteroid (betamethasone valerate 2.250 mg) impregnated into an adhesive plaster (Betesil®), which is specifically indicated for difficult to treat recalcitrant inflammatory skin conditions such as localised chronic psoriasis plaques, eczema, lichenification, granuloma annulare, mycosis fungoides, lichen planus and palmoplantar inflammatory lesions.<sup>2</sup>

## Betamethasone Valerate Medicated Plaster - BMVP (Betesil®)

### What is BMVP (Betesil®)?

Betesil® is a licensed product available in the UK for the management of inflammatory dermatoses which do not respond to less potent topical steroids. The cutaneous effects are due to the anti-inflammatory, anti-pruritic, anti-proliferative and vasoconstrictive properties of its active ingredient betamethasone valerate.<sup>3</sup>

The technically advanced adhesive plaster is intended for difficult to treat areas such as the extensor surfaces

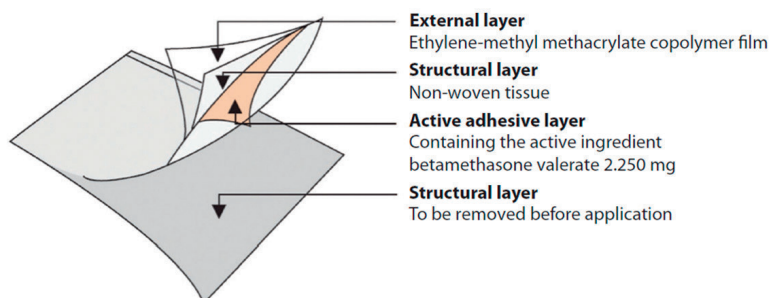
(elbows, knees, anterior skin of tibia and heels) and offers controlled sustained release of betamethasone valerate 2.250 mg for a period of up to 24 hours.

### What is the clinical evidence?

The LIBERE study was an open label, multicentre, prospective, observational study for BMVP in persons with any inflammatory dermatoses amounting to less than 5% of the body surface area. 258 respondents were recruited, the majority of which had psoriasis (49%), eczema (34%), or other dermatoses (17%). Pre and post treatment clinical evaluations included disease severity, using the Physician Global Assessment (PGA) score, patient satisfaction and Quality of Life using the Dermatology Life Quality Index (DLQI). The BMVP

**Betesil® can be applied once daily to specific inflammatory lesions, on not more than 5% of total BSA**

Figure 1. Schematic structure of BVMP.



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**Note:** This image shows the application of a placebo plaster. For application guidance always refer to the SmPC or PIL. Cutting techniques are available at [betesil.co.uk](http://betesil.co.uk).

was applied daily for up to 4 weeks as per manufacturer's recommendations. Results indicated that betamethasone valerate medicated plaster was well-tolerated and effective in the treatment of inflammatory dermatoses, improving clinical signs as well as patients' quality of life. The greatest improvement in clinical assessment and DLQI reported by respondents was with eczema. Respondents reported the BMVP was more effective than previous therapies (93.5% very satisfied and 90.4% satisfied), and ease of use and rapidity of application were rated as good or very good.<sup>4</sup>

An early phase I safety study on healthy individuals demonstrated that following repeated BMVP patch tests over 19 days, whereby the BMVP patches were applied for 24 and 48 hours, no detectable concentrations of

### **The flexibility of the plaster lends itself to application over lesions on skin and joints subject to increased movement such as the elbows and knees**

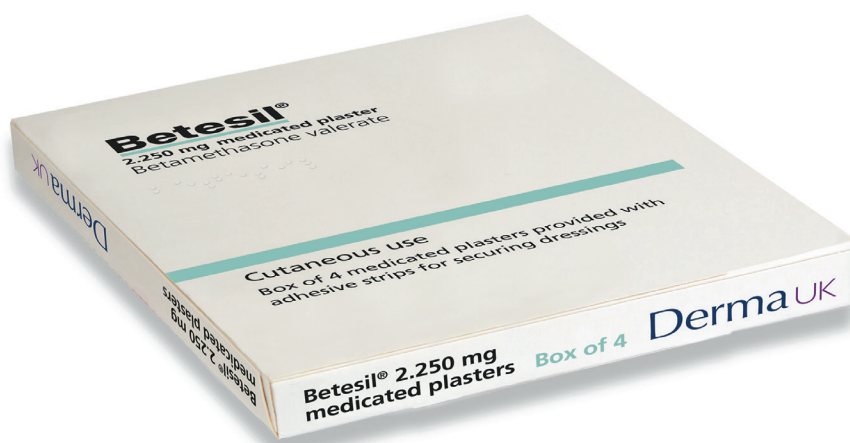
BMV were found in any of the blood tests of healthy respondents.<sup>5</sup>

Safety of BMVP studies have also been undertaken with persons with psoriasis. Following repeated applications, blood plasma levels of BMV were deemed to be lower than normal blood cortisol levels and therefore too low to cause any systemic toxic effects.<sup>6</sup>

Another study explored the bioavailability of BMVP as compared

to the bioavailability of BMV cream, with and without occlusion, following repeated applications. Results indicated that the percutaneous absorption of BMV from the plaster applications was noted to be below the limit of quantification (0.5 mg/ml) in about half of the subjects in that treatment group. Percutaneous absorption of BMV cream group was below the limit of quantification in all but one subject. Researchers concluded that although the bioavailability of BMV is higher in the plaster application group, levels of active substance remained very limited.<sup>7</sup>

A safety and efficacy randomised controlled trial demonstrated that BMVP was more efficacious than BMV cream with a statistically significant difference ( $p < 0.001$  versus BMV cream) in clearance of mild to moderate



plaque psoriasis at 3 weeks, which was sustained at 5 weeks. No differences were demonstrated in safety as assessed by reported adverse events.<sup>8</sup>

A large multicentred, prospective, assessor blinded, randomised controlled trial compared BMVP with calcipotriol-betamethasone dipropionate fixed dose combination ointment over a 4 week treatment period. 324 patients with psoriasis were recruited. Researchers concluded that both treatments significantly improved patients' psoriasis and Quality of Life. Results also demonstrated the BMVP is non-inferior to calcipotriol-betamethasone dipropionate fixed dose combination ointment, and significant QOL improvement was also preserved during the 8 week follow up period.<sup>9</sup>

A small, phase II, single centre, randomised, investigator blinded, 'within patient' comparator, 4 week study was undertaken. BMVP was compared with calcipotriol-betamethasone dipropionate aerosol foam covered with non-occlusive gauze in 35 patients with psoriasis (SPC states avoid occlusive dressings).<sup>10</sup> Results demonstrated that both treatments were well tolerated with calcipotriol-betamethasone dipropionate foam showing superior efficacy in total clinical scores (sum of erythema, scaling and infiltration scores).<sup>11</sup> However, as this was a small scale study, further research is required.

A recent review of the role of BMVP 2.250 mg in the management of psoriasis and other dermatoses was

published and identified the clinical benefits as being increased controlled release and penetration of active ingredient into the area requiring treatment, enhanced skin hydration and protection from trauma or scratching.<sup>3</sup>

Assessment of efficacy for potent BMVP (potent corticosteroid) with fludrocortide tape (moderately potent corticosteroid), and with other potent topical corticosteroid creams or ointments under occlusion with different dressings would not be relevant comparators, because mode of delivery and absorption rates differ.

#### Is the product easy to use?

Betesil® can be applied once daily to specific inflammatory lesions, on not more than 5% of total BSA. The plaster can be cut to shape to fit the lesions exactly, left in situ for 24 hours, then removed prior to bathing or showering before the next application. Subsequent daily applications can be applied for up to 30 days. The manufacturers advise 30 minutes between each application. The quite gentle adhesive properties aid with preventing cell stripping, and the outer surface of the plaster acts as a barrier and reduces any peeling or friction from clothing or movement. In my recent use of the product I experienced no issues in cutting to size, or application. Mobile extensor surfaces such as the elbow, knees and heel may require additional adhesive tape to secure the plaster in place for 24 hours. Evidence supports this, with research findings indicating it is easier to use, particularly on difficult to treat areas such as the elbows and knees.<sup>3</sup>

#### When not to use Betesil®?

Betesil® is contraindicated if there is any hypersensitivity to the active ingredient or any excipients. Avoid application on any lesions considered to be bacterial, viral or fungal. This includes tuberculosis of the skin, herpes simplex and herpes zoster. It is also contraindicated for inflammatory lesions such as acne, rosacea, perioral dermatitis as well as ulcers, burns and frostbite. Facial use should be avoided. It should not be used on patients under 18.<sup>2</sup>

#### Is Betesil® a high-quality product?

Betesil® feels like a high-quality product, well packaged, with individual plasters contained in individual foil sachets. The colourless, translucent plasters are flexible and adhere readily to clean dry skin. If using portions of the plaster at any one time, the residual plaster can remain within the packaging for subsequent applications. An open foil plaster pack can be used for up to 1 month before discarding. An unopened plaster pack has a shelf life of 3 years.

#### Have others had a good experience with the product?

In reviewing the literature and evidence surrounding BMVP, patient feedback and satisfaction appear to be high, with many positive comments in the literature regarding improving Quality of Life, ease of use, preference over greasier creams and ointments, less mess, less staining of clothes. Patient preference and choice is always useful in enhancing patient concordance.

#### What are the pros and cons of the product?

Betesil® is recommended for difficult to treat areas and incorporates an innovative technology within the patented plaster, which may well enhance resolution of inflammatory lesions such as psoriasis plaques, eczema and lichenification of the skin. It demonstrates efficacy in clinical trials, is simple to apply, and has a good safety profile. It is the only adhesive product currently available which contains a potent topical corticosteroid (betamethasone valerate), providing sustained release of the active ingredient targeted only on the localised



area over a 24 hour period. This will be a useful addition to the treatments available for recalcitrant inflammatory lesions such as thick chronic psoriasis plaques, chronic lichenified eczema, lichen planus and other dermatoses. The flexibility of the plaster lends itself to application over lesions on skin and joints subject to increased movement such as the elbows and knees. Additional adhesive tape is included to secure the plaster in place over a 24 hour period should this be required.

Potent topical corticosteroids are used with care and caution. The abrupt cessation of potent topical steroids and the potential for rebound is a common concern and requires careful management. BMVP is recommended as a daily application for up to 30 days. In order to avoid stopping abruptly it is recommended that once an appreciable improvement has been obtained, applications of BMVP can be discontinued with the option of continuing treatment with a less potent corticosteroid or emollient.

The cost of any product is an important consideration. The price of Betesil® in the UK is £13.98 per pack. Each pack contains 4 plasters. Each plaster provides a surface area of 7.5cm x 10cm and each plaster can be cut to the dimensions of the lesion being treated. Following cutting, the remaining unused plaster can be returned to the sachet, and once opened the plaster has a shelf life of 1 month. The cost per day is really dependent on the condition being treated and surface area affected.

#### **The cost-effective argument for Betesil® is based on the following factors**

Compared with other topical creams and ointments patient compliance can be enhanced due to the accurate metered dosage delivered over a 24 hour period, specifically to the localised area. This will prevent the user from applying too much or too little BMV. It may help reassure the patient, carer and health professional if steroid phobia is evident.

Persons living with a chronic inflammatory skin condition may prefer the occlusive BMVP as an as easy to

wear, and once a day application which helps hydrate the lesions. Each Betesil® plaster can be cut to size to suit the dimensions of the lesion being treated, thereby avoiding wastage. In addition to this each plaster is individually wrapped for better hygiene.

### **Betesil® is indicated for localised difficult to treat inflammatory dermatoses which have not responded to mild to moderate topical corticosteroid therapy**

A direct cost comparison to fludoxycortide tape is not realistic as the potency of steroid within the tape (moderately potent) and BMV plaster (potent) differs, while clinical indications may also differ. However, Betesil® (4x10cm, £13.98), does appear to be more cost effective when compared to fludoxycortide tape (20cm, £12.49).

#### **Conclusion**

Betesil® is indicated for localised difficult to treat inflammatory dermatoses which have not responded to mild to moderate topical corticosteroid therapy. Research evidence supports safety and efficacy of the BMV impregnated plaster. Besides the patented technology of the medicated plaster, added benefits include once a day application, enhanced hydration of the lesions, protection from trauma and itch and accurate measured dosing of the active ingredient over 24 hours. It represents a useful addition to the armoury of topical treatments available for persons living with chronic inflammatory skin conditions. Betesil® has recently been submitted for listing in the BNF and Derma UK are awaiting confirmation of this. Derma UK are also planning an application to the Scottish Medicines Consortium.

Useful educational tools for health professionals and patients are available online at [www.betesil.co.uk](http://www.betesil.co.uk) and include an application video and a cutting template. **DN**

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