

Betesil[®]

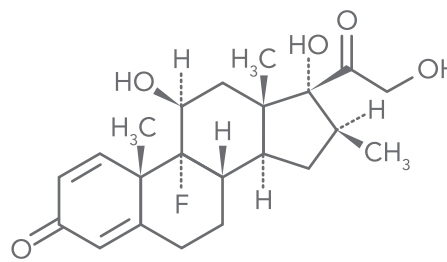
(betamethasone 17-valerate 2.250mg medicated plaster)

PRODUCT DEVELOPMENT RATIONALE

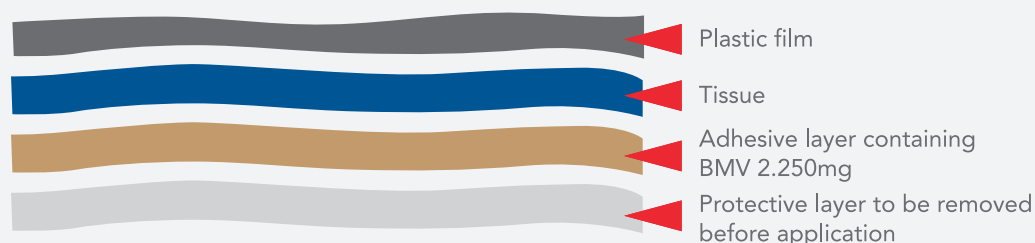
Betamethasone valerate (BMV) (M.W.= 476.57; molecular formula $C_{27}H_{37}FO_6$) is a white powder basically insoluble in water and soluble in alcohol. BMV is a potent glucocorticoid indicated for the treatment of a multitude of severe inflammatory skin disorders.

BMV is currently available only as cream, ointment and lotion, usually at a concentration of 0.1% betamethasone base (equivalent to 0.12% BMV). The availability of a cosmetically acceptable and adhering plaster of BMV may achieve benefits from occlusive medication.

For this reason IBSA Institut Biochimique SA (Lugano, Switzerland) has developed **Betesil[®]**, a transparent, adhesive, medicated plaster 75 cm²-sized (75 x 100mm) containing 2.250mg of BMV as active ingredient, intended for topical use.



Vertical section of **Betesil[®]** plaster



CLINICAL DEVELOPMENT

The clinical development of **Betesil[®]** medicated plaster has been addressed to four main points:

- *systemic absorption after topical application*: the results showed that the average peak concentrations of betamethasone were always under the threshold for a pharmacological effect, therefore the systemic exposure to BMV after cutaneous application of **Betesil[®]** should be considered negligible.
- *comparative efficacy in patients vs reference drug*: the findings indicated a significantly higher therapeutic efficacy of **Betesil[®]** in the treatment of psoriasis showing that the lesions disappeared or reduced to a greater extent if compared to the reference drug thanks to the occlusion of the

lesion, which not only facilitates the healing, but also protects the lesion itself from trauma or scratching; moreover, **Betesil[®]**-treated psoriatic lesions showed a higher hydration. It is also to be mentioned that, besides chronic psoriasis, **Betesil[®]** was successfully investigated in contact dermatitis.

- *local safety*: none of the constituents of **Betesil[®]** acts as contact sensitizer; the adverse events observed after the application of the plasters were those expected for topical corticosteroids and all resolved spontaneously.
- *systemic safety*: no systemic adverse events have been reported with **Betesil[®]**.

THERAPEUTIC INDICATIONS

Betesil[®] is intended for topical application in the treatment of severe inflammatory skin disorders such as eczemas unresponsive to less potent corticosteroids, psoriasis, lichenifications, lichen planus, granuloma annulare, pustolosis palmaris and plantaris, mycosis fungoides and other recalcitrant dermatoses.

Thanks to the adhesive and occlusive characteristics of this new pharmaceutical form, **Betesil**[®] is particularly indicated for the treatment of recalcitrant localized chronic plaque psoriasis, for difficult-to treat areas such as knees, elbows and tibial anterior face.

ADVANTAGES OF THIS NEW FORM

- self adhering plaster suitable for treatment of psoriasis and other corticosteroids-responsive dermatitis which may benefit from an occlusive medication
- uniform distribution and concentration of BMV on the entire affected skin and a proportionality between the BMV dose and the size of the lesion
- protection from local trauma and irritation which are factors that can worsen the disease and delay the healing
- a peeling effect of the horny layers of psoriatic lesions when the plaster is removed, which can help the improvement of the healing itself
- avoiding of the cosmetically unpleasant drawbacks of ointments, such as unctuousity and spotting
- the plaster does not stick to clothes, as it may happen with creams and ointments

Other IBSA's BMV medicated plaster trademarks: Cortiflam[®], Betatape[®].