Inflammatory skin conditions

Potent, Practical medicated plaster

with a uniform metered dose

delivered directly to the affected area

Betesil®

2.250 mg medicated plaster
Betamethasone valerate

Now available in both 4 and 8 pack cartons

The only medicated plaster containing a potent steroid that **treats, protects,** and provides a **metered dose** for inflammatory skin conditions and plaque psoriasis.[1]

BETESIL is indicated in adults for the treatment of inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as eczema, lichenification, lichen planus, granuloma annulare, palmoplantar pustulosis and mycosis fungoides. Also suitable for chronic plaque psoriasis localized in difficult to treat areas (e.g. knees, elbows and anterior face of the tibia on an area not greater than 5% of the body surface). For further details please see the Betesil® 2.250 mg medicated plaster Summary of Product Characteristics (SmPC).

Betesil®
2.250 mg medicated plaster
Betamethasone valerate

Another trusted product from
dermauk.co.uk

Derma UK

Diagnosis

BETESIL is indicated in adults for inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as

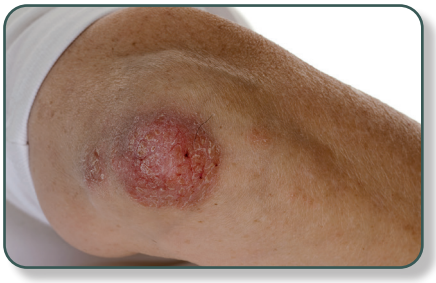
- eczema
- lichenification
- lichen planus
- granuloma annulare
- palmoplantar pustulosis
- mycosis fungoides.[1]

Also, treatment of chronic plaque psoriasis in difficult-to-treat areas (such as knees, elbows and shins) on a maximum of 5% of the total body surface area.

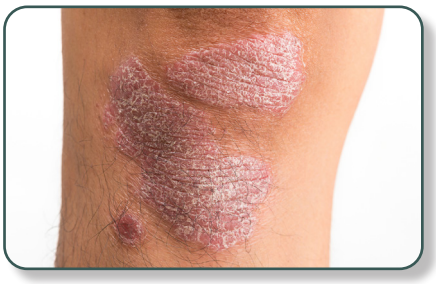
BETESIL in a medicated plaster form provides Betamethasone valerate under occlusion and an alternative method of administration.

Once a significant improvement has been achieved, it may be replaced by another form of less potent corticosteroid.

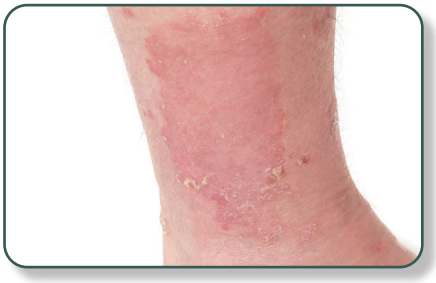
Elbows



Knees

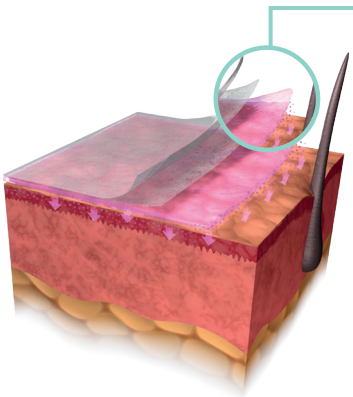


Shins OR anterior face of the tibia



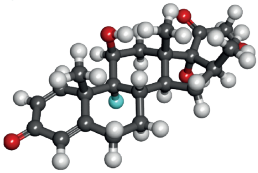
Uniform metered dose

A uniform metered dose of Betamethasone valerate



For action targeted on the lesion

- The medicated plaster contains **2.250 mg** of Betamethasone valerate



- Action is targeted specifically on the application area

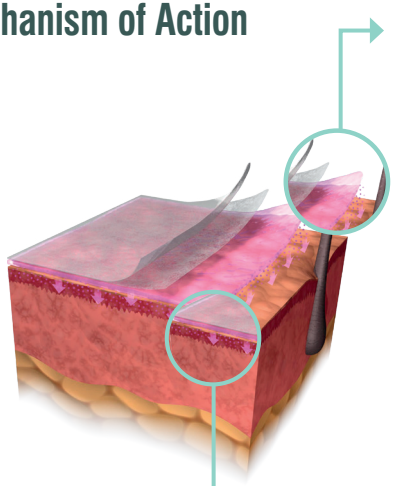
- 1 plaster lasts 24 hours*

*Max daily dose 6 plasters,
Max treatment period 30 days

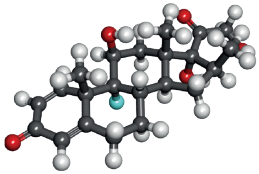
Betesil®
2.250 mg medicated plaster
Betamethasone valerate

Treatment

Mechanism of Action



Betamethasone valerate



Localised, uniform concentration of Betamethasone valerate[1]

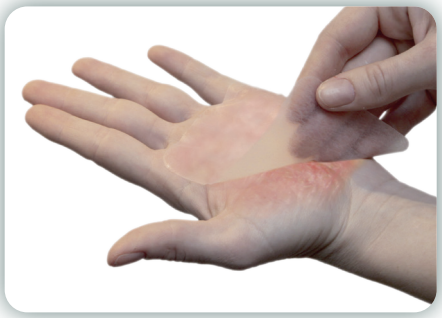
Potent Action

- Anti-inflammatory
- Anti-itch
- Vasoconstrictive

Betamethasone valerate is held back by the stratum corneum[1]

Only small amounts reach the dermis where it can be absorbed[1]

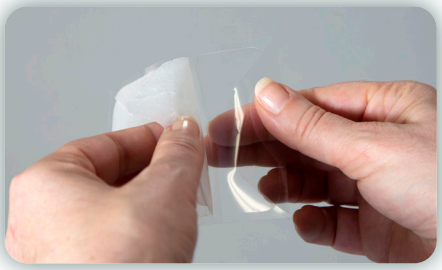
Advantages of BETESIL Medicated Plaster



- An **accurate metered dose** of steroid due to its pharmaceutical form
- **Protection of the lesion** via a medicated plaster
- **Superior efficacy** versus Betamethasone cream[2, 3]
- **Occlusive**, aids skin rehydration and fast healing
- **Gentle adhesion**, minimal cell-stripping
- **Efficacy equivalent** to Calcipotriol-Betamethasone dipropionate (50 μg - 0.5mg/g) ointment[4]

Protecting the Lesion

A protective plaster

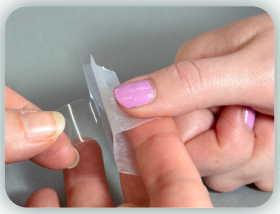


Protecting the lesion

Suitable for hard-to-treat areas

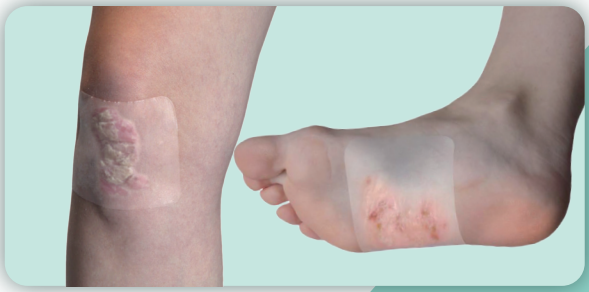
- Knees
- Elbows
- Shins

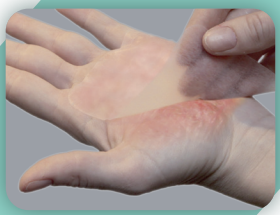
Cut to fit the size of the lesion. Apply the adhesive side of the medicated plaster to the affected area and remove the protective film



Medicated plaster

- Discreet
- Flexible, can be cut to size to fit the area to be treated*
- Easy application
- Does not stain clothes or bedding
- Acts as a barrier, reducing the risk of further damage to the lesion from trauma or scratching[2]





*Visit **betesil.co.uk/HCP** for a selection of downloadable cutting templates and to watch our application video

Betesil®

2.250 mg medicated plaster

Betamethasone valerate

Clinical Studies

NALDI Study in plaque psoriasis[2]: BETESIL more efficacious than Betamethasone Cream 0.1%

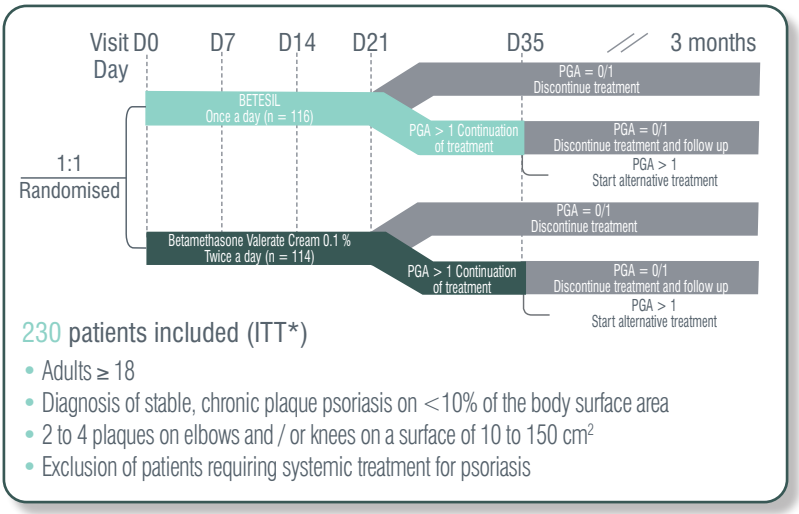
A Prospective and controlled study

International, multi-centre, prospective, randomised, assessor-blind, parallel group, active-controlled phase III study comparing BMV plaster 0.1% versus Betamethasone valerate 0.1% cream.

Objective

To evaluate the efficacy and safety of BETESIL and Betamethasone valerate cream 0.1% in patients with mild-to-moderate chronic plaque psoriasis.

Study Diagram



230 patients included (ITT*)

- Adults ≥ 18
- Diagnosis of stable, chronic plaque psoriasis on <10% of the body surface area
- 2 to 4 plaques on elbows and / or knees on a surface of 10 to 150 cm^2
- Exclusion of patients requiring systemic treatment for psoriasis

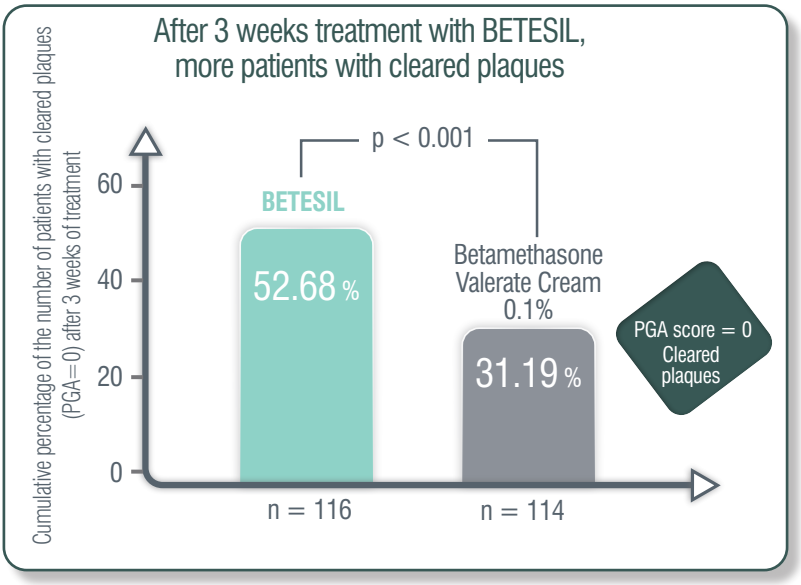
Outcome measures

Number of patients with cleared plaques (PGA score ** = 0) after 3 weeks of treatment (ITT*)

BETESIL like other potent steroids, is a first-line treatment in plaque psoriasis excluding sensitive areas (face and skin folds).

Once a significant improvement has been achieved, it may be replaced by another form of less potent corticosteroid.

Clinical Studies



Equivalent safety

- Safety is equivalent for both treatment groups, with 14 patients presenting with adverse effects in each group. The most common side effects are infections and infestations (6 in the BETESIL group and 7 in the Betamethasone valerate cream 1% group).
- The serious adverse effects (bladder polyps resection, worsening of asthma, fracture of a rib and clavicle) identified in the Betamethasone valerate cream 1% group were not related to treatment. No adverse effects of grade 3-4 have been identified in the BETESIL group.

Known common adverse events (≥ 1/100; ≤ 1/10)

- Skin atrophy
- Erythema
- Papules
- Boils
- Pustules
- Skin erosion
- Telangiectasia
- Pruritus

* ITT: Intent to Treat population

* * PGA: Psoriasis Global Assessment measuring the status of psoriasis where 0 = absent and 5 = severe, scored here between D0 and D21 by blind evaluators based on photographs.

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Betamethasone valerate

Clinical Studies

Ortonne Study in plaque psoriasis: BETESIL is non-inferior versus a combination of Betamethasone 0.5 mg - Calcipotriol 50 µg/g Ointment[4]

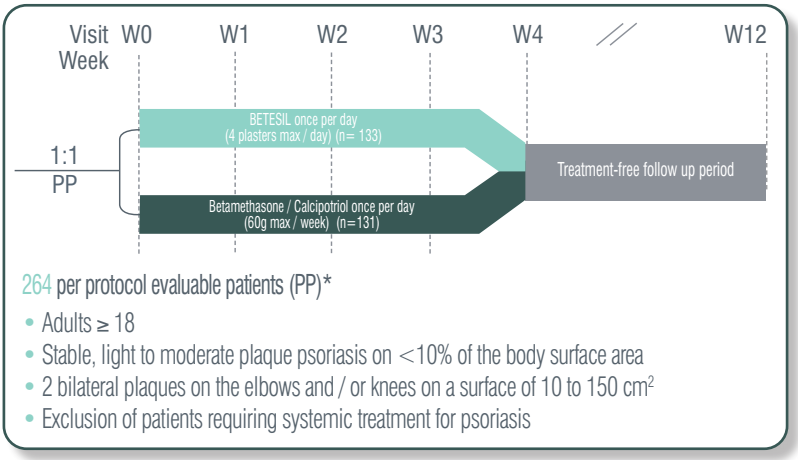
A Prospective and controlled study

Multi-centre, prospective, randomised, investigator-blinded, controlled, non-inferiority trial versus Betamethasone Dipropionate/Calcipotriol combination.

Objective

To demonstrate the non-inferiority of BETESIL once a day versus a combination of Betamethasone 0.5 mg - Calcipotriol 50 µg/g in ointment form in the treatment of chronic mild to moderate plaque psoriasis.

Study Diagram



264 per protocol evaluable patients (PP)*

- Adults ≥ 18
- Stable, light to moderate plaque psoriasis on <10% of the body surface area
- 2 bilateral plaques on the elbows and / or knees on a surface of 10 to 150 cm^2
- Exclusion of patients requiring systemic treatment for psoriasis

Outcome measures

Evaluation of efficacy at 4 weeks of treatment with TSS-4 Global score * * (PP*).

Non-inferiority hypothesis: For BETESIL to be considered not inferior, the lower limit of the 95% confidence interval for the difference between the two treatments must be greater than -1.

BETESIL like other potent steroids, is a first-line treatment in plaque psoriasis excluding sensitive areas (face and skin folds).

Once a significant improvement has been achieved, it should be replaced by another form of steroid and the frequency should be gradually reduced.

Clinical Studies

- Non-significant difference
- CI*** 95% >-1 (non-inferiority margin)

BETESIL is non inferior to the combination of Betamethasone 0.5 mg - Calcipotriol 50 µg/ g

Equivalent safety

- Safety is equivalent for both treatment groups, with the proportion of patients with adverse effects in the BETESIL group being 8.48% (165 patients, ITT population), and in the combination of Betamethasone / Calcipotriol group being 9.43% (159 patients, ITT population)
- The most common adverse effect was nasopharyngitis (2 patients in the BETESIL group and 4 in the Betamethasone/Calcipotriol group)
- Only 1 side effect is related to treatment (burning sensation) in the BETESIL group

* PP: Per protocol.

* * TSS-4: 4-item Total Severity Score: redness/erythema, scale/crusting, thickening/elevation of plaques, pruritus.

* * * CI - Confidence Interval

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Betamethasone valerate

Potency of a topical corticosteroid preparation is a result of the formulation as well as the corticosteroid. Therefore, proprietary names are shown.[5]

Proprietary Name	Generic Name
MILD	**MILD**
Hydrocortisone 0.1–2.5%	Hydrocortisone 0.1-2.5%
Dioderm	Hydrocortisone 0.1%
Mildison	Hydrocortisone 1%
Synalar 1 in 10 dilution	Fluocinolone acetonide 0.0025%
MODERATE	**MODERATE**
Betnovate-RD	Betamethasone valerate 0.025%
Eumovate	Clobetasone butyrate 0.05%
Haelan	Fludroxycortide 0.0125%
Modrasone	Alclometasone dipropionate 0.05%
Synalar 1 in 4 dilution	Fluocinolone acetonide 0.00625%
Ultralanum Plain	Fluocortolone hexanoate 0.25%
POTENT	**POTENT**
Beclometasone dipropionate 0.025%	Beclometasone dipropionate 0.025%
Betamethasone valerate 0.1%	Betamethasone valerate 0.1%
Betacap	Betamethasone valerate 0.1%
Betesil	Betamethasone valerate 0.1%
Bettamousse	Contains 1.2 mg betamethasone valerate 0.1%, per gram
Betnovate	Betamethasone valerate 0.1%
Cutivate Ointment / Cream	Fluticasone propionate 0.005% / 0.05%
Diprosone	Betamethasone dipropionate 0.05%
Elocon	Mometasone furoate 0.1%
Hydrocortisone butyrate	Hydrocortisone butyrate
Locoid	Hydrocortisone butyrate 0.1%
Locoid Crelo	Hydrocortisone butyrate 0.1%
Metosyn	Fluocinonide 0.05%
Mometasone furoate 0.1%	Mometasone furoate 0.1%
Nerisone	Diflucortolone valerate 0.1%
Synalar	Fluocinolone acetonide 0.025%
VERY POTENT	**VERY POTENT**
Clarelux	Clobetasol propionate 0.05%
Dermovate	Clobetasol propionate 0.05%
Etrivex	Clobetasol propionate 0.05%
Nerisone Forte	Diflucortolone valerate 0.3%

Abbreviated Prescribing Information for BETESIL® 2.250 mg medicated plaster

Abbreviated Prescribing Information for BETESIL® 2.250 mg medicated plaster. Please refer to the full Summary of Product Characteristics (SmPC) prior to prescribing.

Presentation: A colourless, medicated plaster, containing 2.250 mg of betamethasone valerate (corresponding to 1.845 mg of betamethasone). **Indications:** Indicated in adults for the treatment of inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as eczema, lichenification, lichen planus, granuloma annulare, palmoplantar pustulosis and mycosis fungoides. Also suitable for chronic plaque psoriasis localized in difficult to treat areas (e.g., knees, elbows, and anterior face of the tibia). Overall, the surface area treated with BETESIL should not exceed 5% of the body surface). **Dosage and Administration:** Apply the medicated plaster to the skin area to be treated once a day. Do not exceed the maximum daily dose of six medicated plasters and the maximum treatment period of 30 days. A new medicated plaster must be applied every 24 hours. Wait at least 30 minutes between one application and the next. Once an appreciable improvement has been obtained, discontinue application, and consider continuing treatment with a less potent corticosteroid. The safety and efficacy in children aged <18 years has not yet been established. For full details of usage please refer to the relevant section of the SmPC. Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Cutaneous tuberculosis and viral skin infections (including vaccinia pustules, herpes zoster and herpes simplex). Exudative lesions and primary skin infections caused by fungi or bacteria (e.g. syphilitic skin lesions). Acne, acne rosacea, perioral dermatitis, skin ulcers, burns and frostbite. Do not apply to face. Do not use on patients under 18 years of age. **Precautions and Warnings:** Caution in patients with visual disturbance. Cataract, glaucoma, or rare diseases such as central serous chorioretinopathy have been reported with systemic and topical corticosteroid use. Use of topical corticosteroids on large areas of the body and for prolonged periods, as well as the use of an occlusive dressing can cause a temporary suppression of the hypothalamus-pituitary-adrenal axis, leading to secondary hypoadrenalism and adrenal hypercorticism, including the Cushing's syndrome. In these situations, treatment should be discontinued gradually and under strict control of a doctor due to the risk of acute adrenal insufficiency. Sudden withdrawal of the treatment in psoriatic patients, may also lead to symptoms exacerbation or generalized pustular psoriasis. Prolonged use in diffuse psoriasis (except for the treatment of isolated plaques) or diffuse eczema or application on lesions located in skin folds is not recommended, as these conditions may increase systemic absorption. The use of occlusive bandages, especially with plastic material, may increase this effect. The symptoms of this are: facial redness, weight changes (fat increase in body and face and loss in legs and arms), reddish streaks on stomach, headache, menstrual alterations, or an increase in unwanted face and body hair. In this regard, it is known that certain skin areas (face, eyelids, armpits, scalp and scrotum) absorb more easily than others (skin on the knees, elbows, palms of the hands and feet on soles). Application of topical medicinal products, especially if prolonged, may give rise to hypersensitivity reaction. Skin atrophy has also been reported after three-week treatment periods. In case of drug intolerance, for example if skin irritation or contact dermatitis occurs during treatment, it is necessary to stop the medicated plaster application and start suitable treatment (see section 4.8 of the SmPC, "Undesirable effects"). Corticosteroids may affect the results of the nitroblue tetrazolium test (NBT) for diagnosing bacterial infections by producing false negatives. Medicinal products containing corticosteroids must be used with caution in patients with impaired immune system function (T-lymphocytes) or in those being treated with immunosuppressive therapy. The product contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause hypersensitivity reactions (possibly delayed). There are no or limited amount of data from the use of betamethasone valerate in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). Betesil is not recommended during pregnancy and in women of childbearing potential not using contraception. **Undesirable effects:** Commonly reported side effects are skin and subcutaneous tissue disorders, occurring in about 15% of patients treated. All cases reported during controlled clinical trials were found to be common (≥1/100, <1/10): skin atrophy, telangiectasia, pustules, papules, furuncle, erythema, pruritus, skin erosion. These undesirable effects are local effects on the skin in the plaster application area. No systemic effects have been observed. Prescribers should consult the summary of product characteristics for other more general considerations on side effects reported with use of corticosteroids for cutaneous use. **Precautions for Storage:** Do not store above 25°C. Store the medicated plaster in its original sachet to preserve its integrity. For storage conditions after first opening of the medicinal product, see SmPC. **Legal Category:** POM. **Package Quantities:** A carton containing four or eight envelopes, each envelope contains one 7.5 cm x 10 cm medicated plaster containing 2.250 mg of betamethasone valerate. **Marketing Authorisation Number and Holder:** PL 21039/0009. IBSA FARMACEUTICI ITALIA S.R.L. VIA MARTIRI DI CEFALONIA 2 LODI -26900 ITALY. **Basic NHS Price:** £13.98 per pack of four BETESIL® 2.250 mg medicated plasters. £27.46 per pack for eight BETESIL® 2.250 mg medicated plasters. **Date of preparation of Prescribing Information:** December 2021.

Further information can be found in the Summary of Product Characteristics or from: Derma UK Ltd, The Toffee Factory, Lower Steenbergs Yard, Quayside, Ouseburn, Walker Rd, Newcastle upon Tyne, Tyne and Wear, NE1 2DF.

Adverse events should be reported.
Information about adverse event reporting can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Derma UK Ltd, UK on 0191 375 9020.

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Betamethasone valerate

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The only medicated plaster containing a potent steroid that **treats, protects,** and provides a **metered dose** for inflammatory skin conditions and plaque psoriasis.(1)

How Often?
1 plaster per plaque every 24 hours

How Many?
6 plasters/day maximum

Secure?
Adhesive strips included for securing dressings

What's in the pack?
Box of 4 or 8 medicated plasters (10 x 7.5 cm)

Maximum Treatment?
30 days until plaque improves, then if needed continue treatment with a less potent corticosteroid

(1) Derma UK Ltd., 'Summary of Betesil® Product Characteristics (SmPC).' 2021

(2) Naldi L et al., 'Efficacy and Safety of the Betamethasone Valerate 0,1% Plaster in Mild-to-Moderate Chronic Plaque Psoriasis: A Randomized, Parallel-Group, Active-Controlled, Phase III Study.' *American Journal of Clinical Dermatology*, vol. 12, no 3, 2011, pp. 191-2011.

(3) Pacifico A et al., 'A new formulation of an occlusive dressing containing betamethasone valerate 0.1% in the treatment of mild to moderate psoriasis.' *Journal of European Academy of Dermatology and Venereology*, no 20, 2006, pp. 153-157.

(4) Ortonne JP, et al., 'Betamethasone valerate dressing is non-inferior to calcipotriol-betamethasone dipropionate ointment in the treatment of patients with mild-to-moderate chronic plaque psoriasis: results of a randomized assessor-blinded multicentre trial.' *Journal of European Academy of Dermatology and Venereology*, vol. 28, no 9, 2014, pp. 1226-34.

(5) National Institute for Health and Care Excellence, Topical corticosteroids, National Institute for Health and Care Excellence, https://bnf.nice.org.uk/treatment-summary/topical-corticosteroids.html, (accessed 24th November 2021).

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2.250 mg medicated plaster
Betamethasone valerate

BET/82/1121

Date of preparation: December 2021.