

## Calcipotriol/Betamethasone 50 micrograms/g + 0.5 mg/g Gel– Abbreviated Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Calcipotriol/Betamethasone 50 micrograms/g + 0.5 mg/g Gel

One gram of gel contains 50 micrograms of calcipotriol and 0.5 mg of betamethasone. **Uses** Topical treatment of scalp psoriasis in adults. Topical treatment of mild to moderate “non-scalp” plaque psoriasis vulgaris in adults. **Dosage and Administration** Calcipotriol/Betamethasone gel should be applied to affected areas once daily. The recommended treatment period is 4 weeks for scalp areas and 8 weeks for “non-scalp” areas. If it is necessary to continue or restart treatment after this period, treatment should be continued after medical review and under regular medical supervision. When using calcipotriol containing medicinal products, the maximum daily dose should not exceed 15 g. The body surface area treated with calcipotriol containing medicinal products should not exceed 30 %. All the affected scalp areas may be treated with Calcipotriol/Betamethasone gel. An amount between 1 g and 4 g per day is usually sufficient for treatment of the scalp. Should not be applied directly to the face or eyes. Not recommended to take a shower or bath, or to wash the hair in case of scalp application, immediately after application. Gel should remain on the skin during the night or during the day. Bottle should be shaken before use. Hands should be washed after use. Not evaluated in patients with severe renal insufficiency or severe hepatic disorders. Not recommended in children and adolescents. **Special Warnings and Precautions** Calcipotriol/Betamethasone gel contains a potent group III steroid and concurrent treatment with other steroids must be avoided. Adverse reactions found in connection with systemic corticosteroid treatment may occur also during topical corticosteroid treatment due to systemic absorption. Application under occlusive dressings, on large areas of damaged skin, mucous membranes, skin folds should be avoided. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for a referral to an ophthalmologist. Hypercalcaemia may occur if the maximum daily dose (15 g) is exceeded. Should not be used on face or genitals. When lesions become secondarily infected, they should be treated with antimicrobiological therapy. If infection worsens, treatment with corticosteroids should be stopped. When treating psoriasis there may be a risk of generalised pustular psoriasis or of rebound effects when discontinuing treatment. Increased risk of local and systemic corticosteroid adverse reactions with long term use. No experience with the use of Calcipotriol/Betamethasone gel in guttate psoriasis. Recommended to limit or avoid excessive exposure to either natural or artificial sunlight. Topical calcipotriol should be used with UVR only if the potential benefits outweigh the potential risks. Calcipotriol/Betamethasone gel contains butylhydroxytoluene (E321) as an excipient which may cause local skin reactions, or irritation to the eyes and mucous membranes. Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered. **Contraindications** Hypersensitivity to the active substances or to any of the excipients, erythrodermic, exfoliative and pustular psoriasis, known disorders of calcium metabolism, viral lesions of the skin, fungal or bacterial skin infections, parasitic infections, skin manifestations in relation to tuberculosis, perioral dermatitis, atrophic skin, striae atrophicae, fragility of skin veins, ichthyosis, acne vulgaris, acne rosacea, rosacea, ulcers and wounds. **Interactions with other medicinal products** No interaction studies have been performed with Calcipotriol/Betamethasone gel. **Pregnancy fertility and Lactation** The potential risk for humans is uncertain. Therefore, during pregnancy Calcipotriol/Betamethasone gel should only be used when the potential benefit justifies the potential risk. Caution should be exercised when prescribing to women who breast-feed. Not to be used on the breast when breast-feeding. **Side Effects** Common: pruritis. Refer to SmPC for a full list of side effects. **Overdose** Use above the recommended dose may cause elevated serum calcium which subsides when treatment is discontinued. Excessive prolonged use of topical corticosteroids may suppress the

pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. In case of chronic toxicity, the corticosteroid treatment must be discontinued gradually. **Effects on the ability to drive and/or operate machines** No or negligible influence on the ability to drive and use machines. **Legal category** POM **Pack size** 60 g high-density polyethylene bottle with low-density polyethylene nozzle and a high-density polyethylene screw cap. The bottles are placed in cartons. **Shelf life** 3 years, 6 months after opening. **NHS price** £27.44 for 60g bottle. **Marketing Authorisation Holder** Stirling Anglian Pharmaceuticals Ltd, Hillington Park Innovation Centre, 1 Ainslie Road, Hillington Park, Glasgow G52 4RU **Marketing Authorisation Number** PL 42582/0017  
Further information is available at [medinfo@stirlinganglianpharmaceuticals.com](mailto:medinfo@stirlinganglianpharmaceuticals.com) or **0330 1359 499** **Date of preparation:** March 2026

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**Adverse events should be reported.** Reporting forms and information can be found at <http://yellowcard.mhra.gov.uk> or downloaded from Google Play or the Apple App store. Adverse events should also be reported to **Stirling Anglian Pharmaceuticals** on **0330 1359 499** or by emailing [medinfo@stirlinganglianpharmaceuticals.com](mailto:medinfo@stirlinganglianpharmaceuticals.com)