Dovobet® (calcipotriol/betamethasone) Ointment Prescribing Information for the United Kingdom

Prescribing Information for Dovobet® (calcipotriol/betamethasone) 50 microgram/g + 0.5 mg/g ointment
Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.org.uk/emc) before prescribing.
Indications: Topical treatment of stable plaque psoriasis vulgaris amenable to topical therapy in adults. **Active ingredients:** 50 µg/g calcipotriol (as monohydrate) and 0.5 mg/g betamethasone (as dipropionate). Dosage and administration: Apply to affected area once daily. Recommended treatment period is 4 weeks. There is experience with repeated courses of Dovobet ointment up to 52 weeks. If it is necessary to continue or restart treatment after 4 weeks, continue after medical review and under regular medical supervision. When using calcipotriol containing medicinal products the maximum dose should not exceed 15 g/day. Treated area should not exceed 30% of body surface. Safety and efficacy in children under 18 years have not been established. Safety and efficacy in severe renal insufficiency or severe hepatic disorders have not been evaluated. It is not recommended to take a shower or bath immediately after application. **Contraindications:** Hypersensitivity to any constituents. Erythrodermic, exfoliative or pustular psoriasis. Patients with known calcium metabolism disorders. Viral skin lesions, 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. **Precautions and warnings:** Avoid concurrent treatment with other steroids. Adrenocortical suppression or impact on the metabolic control of diabetes mellitus may occur. Avoid application on large areas of damaged skin, under occlusive dressings or on mucous membranes or skin folds, as it increases the systemic absorption of corticosteroids. Do not use on the skin of the face or genitals. 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 for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Due to the content of calcipotriol, hypercalcaemia may occur. Serum calcium is normalised when treatment is discontinued. The risk of hypercalcaemia is minimal when the maximum daily dose of Dovobet (15 g) is not exceeded. Dovobet contains a potent group III-steroid and concurrent treatment with other steroids on the same treatment area must be avoided. The skin on the face and genitals is very sensitive to corticosteroids. Dovobet should not be used in these areas. Avoid inadvertent transfer to scalp, face, mouth and eyes. Wash hands after applying. If lesions become secondarily infected, they should be treated with antimicrobiological therapy. However, if infection worsens, treatment with corticosteroids should be discontinued. When treating psoriasis with topical corticosteroids, there may be a risk of generalised pustular psoriasis or of rebound effects when discontinuing treatment. With long-term use there is an increased risk of local and systemic corticosteroid adverse reactions in which case treatment should be discontinued. There is limited experience of use of the ointment on the scalp. No experience of use in guttate psoriasis. There is limited experience of concurrent use with other anti-psoriatic products administered topically (to the same treatment area) or systemically or with phototherapy. Physicians are recommended to advise patients to limit or avoid excessive exposure to natural or artificial sunlight. Use with UV radiation only if the physician and patient consider that the potential benefits outweigh the potential risks. Contains butylhydroxytoluene (E321) which may cause local skin reactions or irritation to the eyes and mucous membranes. **Fertility, pregnancy and lactation:** Only use in pregnancy when potential benefit justifies potential risks. Caution when prescribed for women who breast feed. Instruct patient not to use on breast when breast-feeding. **Side effects:** Skin exfoliation, pruritus. Additional undesirable effects observed for calcipotriol and betamethasone: Calcipotriol: application site reactions, pruritus, skin irritation, burning and stinging sensation, dry skin, erythema, rash, dermatitis, eczema, psoriasis aggravated, photosensitivity and hypersensitivity reactions including very rare cases of angioedema and facial oedema. Hypercalcaemia or hypercalciuria may occur very rarely. Betamethasone: local reactions, especially during prolonged application including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, colloid milia, and generalised pustular psoriasis. Systemic reactions are rare; adrenocortical suppression, cataract, infections, impact on the metabolic control of diabetes mellitus and increase of intra-ocular pressure can occur. Systemic reactions occur more frequently when applied under occlusion (skin folds, plastic), to large areas and during long term treatment. **See SmPC for a full list of side effects. Legal category:** POM. **Marketing authorisation number and holder:** PL 05293/0003. LEO Pharma A/S, Ballerup, Denmark. **Basic NHS price:** £19.84/30 g, £39.68/60 g, £73.86/120 g. **Last revised:** April 2023. **Reference number:** REF-23230.

Reporting of Suspected Adverse Reactions

Adverse events should be reported.

Reporting forms and information can be found at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Drug Safety at LEO Pharma by calling +44 (0)1844 347333 or e-mail: medical-info.uk@leo-pharma.com

Further information can be found in the Summary of Product Characteristics or from:
LEO Pharma, Building 5, Foundation Park, Roxborough Way, Maidenhead, Berkshire SL6 3UD, UK.
e-mail: medical-info.uk@leo-pharma.com

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