Abbreviated Prescribing Information for Dovobet® 50 microgram/g + 0.5 mg/g gel

Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.org.uk/emc) before prescribing.

Indications: Topical treatment of scalp psoriasis in adults. Topical treatment of mild to moderate 'non-scalp' plaque psoriasis vulgaris in adults.

Active ingredients: 50 µg/g calcipotriol (as monohydrate) and 0.5 mg/g betamethasone (as dipropionate).

Dosage and administration: Apply to affected areas once daily. Recommended treatment period is 4 weeks for scalp 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 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 patients with severe renal insufficiency or severe hepatic disorders have not been evaluated. Do not apply directly to the face or eyes. It is not recommended to take a shower or bath, or to wash the hair in case of scalp application, immediately after application as the gel should remain on the skin during the night or day. If used on the scalp usually between 1 g and 4 g/day is sufficient. Applicator: Prior to first use, the cartridge and the applicator head must be assembled. After priming, each full actuation delivers 0.05 g of Dovobet gel. Wash hands after use if gel gets on the fingers. Read detailed instructions for use in package leaflet. Bottle: Shake before use. Wash hands after use.

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. Do not use on the skin of the face or genitals. Avoid inadvertent transfer to face, mouth and eyes. Wash hands after applying. There may be a risk of generalised pustular psoriasis. With long-term use there is an increased risk of local and systemic corticosteroid adverse reactions in which case treatment should be discontinued. There may be a risk of rebound when discontinuing treatment. 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 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 risk. Caution when prescribed for women who breast-feed. Instruct patient not to use on breast when breast-feeding.

Side effects: Pruritus. Additional undesirable effects observed for calcipotriol and betamethasone: Calcipotriol: application site reactions, 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 appear very rarely. Betamethasone: local reactions, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, colloid milia, generalised pustular psoriasis, infections. 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 05293/0005. LEO Pharma A/S, Ballerup, Denmark.

Basic NHS price: Bottle: £37.21/60 g, £69.11/2 x 60 g. Applicator: £37.21/60 g.

Last revised: July 2015.

Further information can be found in the Summary of Product Characteristics or from: LEO Pharma, Horizon, Honey Lane, Hurley, Berkshire SL6 6RJ. e-mail: medical-info.uk@leo-pharma.com

Reporting of Suspected Adverse Reactions
Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard.

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

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