Dermatology
beyond the skin

LEO Pharma Meeting

"Managing Common Skin Conditions in Primary Care - My Approach to Treating Acne, Eczema and Psoriasis"

Evening of Thursday 15th October
Virtual Live Webinar with Dr George Moncrieff, FRCP FRCGP
Past PCDS Committee Member 2005 - 2018
Past Chair of Dermatology Council England 2014 - 2018
Primary Care Advisor to the National Eczema Society

Agenda

19:15-19:20	**Welcome & Introduction** LEO Pharma
19:20-19:30	**Chair Rita Bali (LPC lead for Cambridgeshire)- Creating Pharmacist Networks**
19:30-20:30	**"Managing Common Skin Conditions in Primary Care - My Approach to Treating Acne, Eczema and Psoriasis"** Dr George Moncrieff, GPwER Clinical Lead for South Birmingham Dermatology Clinic SDS and MyHealthCare Federation Former Chair of Dermatology Council England
20:30-20:45	**Questions and Close**

To reserve your place at this meeting please email Dianne Stewart at dcruk@leo-pharma.com or alternatively contact me on the following mobile number **07887657707**

"Virtual meeting" by way of a secure link which will be sent to you with full joining instructions
This meeting is organised and funded by LEO Pharma for UK/IE healthcare practitioners.
Prescribing Information for Enstilar® (calcipotriol/betamethasone dipropionate) cutaneous foam can be found overleaf.

UK/IE MAT-38846
September 2020

Abbreviated Prescribing Information for Enstilar® (calcipotriol/betamethasone) 50 micrograms/g + 0.5 mg/g cutaneous foam. Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.org.uk/emc or www.medicines.ie) before prescribing. **Indication:** Topical treatment of psoriasis vulgaris in adults. 2/5
Active ingredients: 50 µg/g calcipotriol (as monohydrate) and 0.5 mg/g betamethasone (as dipropionate). **Dosage and administration:** Apply by spraying onto affected area once daily. Recommended treatment period is 4 weeks. The daily maximum dose of Enstilar should not exceed 15 g, i.e. one 60 g can should last for at least 4 days. 15 g corresponds to the amount administered from the can if the actuator is fully depressed for approximately one minute. A two-second application delivers approximately 0.5 g. As a guide, 0.5 g of foam should cover an area of skin roughly corresponding to the surface area of an adult hand. If using other calcipotriol-containing medical products in addition to Enstilar, the total dose of all calcipotriol-containing products should not exceed 15 g per day. Total body surface area treated should not exceed 30%. Safety and efficacy in patients with severe renal insufficiency or severe hepatic disorders have not been evaluated. Safety and efficacy in children below 18 years have not been established. Shake the can for a few seconds before use. Apply by spraying, holding the can at least 3 cm from the skin, in any orientation except horizontally. Spray directly onto each affected skin area and rub in gently. If used on the scalp, spray into the palm of the hand then apply to affected scalp areas with the fingertips. See hair washing instructions in the package leaflet. Wash hands after use (unless Enstilar is used to treat the hands) to avoid accidentally spreading to other parts of the body. Avoid application under occlusive dressings since systemic absorption of corticosteroids increases. It is recommended not to take a shower or bath immediately after application. Let the foam remain on the scalp and/or skin during the night or during the day. **Contraindications:** Hypersensitivity to the active substances or any of the excipients. Erythrodermic and pustular psoriasis. Patients with known disorders of calcium metabolism. Viral (e.g. herpes or varicella) 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:** Adverse reactions found in connection with systemic corticosteroid treatment, e.g. adrenocortical suppression or impaired glycaemic control of diabetes mellitus, may occur also during topical corticosteroid treatment due to systemic absorption. Application under occlusive dressings should be avoided since it increases the systemic absorption of corticosteroids. Application on large areas of damaged skin, or on mucous membranes or in skin folds should be avoided since it increases the systemic absorption of corticosteroids. 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 Enstilar (15 g) is not exceeded. Enstilar contains a potent group III-steroid and concurrent treatment with other steroids on the same treatment area must be avoided. Skin on the face and genitals are very sensitive to corticosteroids. Enstilar should not be used in these areas. Instruct the patient in the correct use of the product to avoid application and accidental transfer to the face, mouth and eyes. Wash hands after each application to avoid accidental transfer to these areas. When 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 rebound effects when discontinuing treatment. Medical supervision should therefore continue in the post-treatment period. Long-term use of corticosteroids may increase the risk of local and systemic adverse reactions. Treatment should be discontinued in case of adverse reactions related to long-term use of corticosteroid. There is no experience with the use of Enstilar in guttate psoriasis. During Enstilar treatment, physicians are recommended to advise patients to limit or avoid excessive exposure to either natural or artificial sunlight. Topical calcipotriol should be used with UVR only if the physician and patient consider that the potential benefits outweigh the potential risks. Enstilar contains butylhydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. **Pregnancy and lactation:** There are no adequate data from the use of Enstilar in pregnant women. Enstilar should only be used during pregnancy when the potential benefit justifies the potential risk. Caution should be exercised when prescribing Enstilar to women who breast-feed. The patient should be instructed not to use Enstilar on the breast when breast-feeding. **Side effects:** There are no common adverse reactions based on the clinical studies. The most frequently reported adverse reactions are application site reactions. Uncommon (≥1/1,000 to <1/100): Folliculitis, hypersensitivity, hypercalcaemia, skin hypopigmentation, rebound effect, application site pruritus, application site irritation. Not known (cannot be estimated from available data): Blurred vision, hair colour changes. *Calcipotriol:* Adverse reactions include application site reactions, pruritus, skin irritation, burning and stinging sensation, dry skin, erythema, rash, dermatitis, psoriasis aggravated, photosensitivity and hypersensitivity reactions, including very rare cases of angioedema and facial oedema. Systemic effects after topical use may appear very rarely causing hypercalcaemia or hypercalciuria. *Betamethasone:* Local reactions can occur after topical use, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation and colloid milia. When treating psoriasis with topical corticosteroids, there may be a risk of generalised pustular psoriasis. Systemic reactions due to topical use of corticosteroids are rare in adults; however, they can be severe. Adrenocortical suppression, cataract, infections, impaired glycaemic control of diabetes mellitus, and increase of intra- ocular pressure can occur, especially after long-term treatment. Systemic reactions occur more frequently when applied under occlusion (plastic, skin folds), when applied on large areas, and during long-term treatment. **Precautions for storage:** Do

not store above 30°C. Extremely flammable aerosol. Pressurised container. May burst if heated. Protect from sunlight. Do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source. Keep away from sparks/open flames. No smoking. **Legal category:** POM.
3/5
Marketing authorisation number and holder: PL 05293/0008 (UK), PA 1025/5/1 (Ireland). LEO Pharma A/S, Ballerup, Denmark. **Basic NHS price (UK):** £39.68/60 g, £79.36/2 x 60 g **Last revised:** October 2019
Reporting of Suspected Adverse Reactions
Adverse events should be reported.
For the United Kingdom, 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
For the Republic of Ireland, reporting forms and information can be obtained from: HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.
Adverse events should also be reported to Drug Safety at LEO Pharma by calling +353 1 4908924 or e-mail: medical-info.ie@leo-pharma.com
Further information can be found in the Summary of Product Characteristics or from:
LEO Pharma, Horizon, Honey Lane, Hurley, Berkshire SL6 6RJ, UK.
e-mail: medical-info.uk@leo-pharma.com/LEO Pharma, Cashel Road, Dublin 12, Ireland. e-mail: medical-info.ie@leo-pharma.com

Abbreviated Prescribing Information for Dovobet® (calcipotriol/betamethasone) 50 microgram/g + 0.5 mg/g gel Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.org.uk/emc or www.medicines.ie) 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 for treatment. 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. 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. 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 (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 risk. Caution when prescribed for women who breast-feed. Instruct patient not to use on breast when breast-feeding. **Side effects:** Common (≥1/100 to <1/10): Pruritus. Uncommon (≥1/1,000 to <1/100): Skin infection, folliculitis, eye irritation, exacerbation of psoriasis, dermatitis, erythema, rash (including erythematous and pustular), acne, skin burning sensation, skin irritation, dry skin, application site pain. Rare (≥1/10,000 to <1/1,000): Hypersensitivity, skin striae, skin exfoliation, rebound effect. Not known (cannot be estimated from available data): Blurred vision, hair colour changes (transient discolouration of the hair at scalp application site). Adverse reactions related to pharmacological class 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. **Legal category:** POM. **Marketing authorisation number and holder:** PL 05293/0005 (UK), PA 1025/1/2 LEO Pharma A/S, Ballerup, Denmark **Basic NHS price (UK):** Bottle: £37.21/60 g, £69.11/2 x 60 g. Applicator: £37.21/60 g. **Last revised:** August 2018.

Reporting of Suspected Adverse Reactions

Adverse events should be reported.

For the United Kingdom, 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

For the Republic of Ireland, reporting forms and information can be obtained from: HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

Adverse events should also be reported to Drug Safety at LEO Pharma by calling +353 1 4908924 or e-mail: medical-info.ie@leo-pharma.com

Further information can be found in the Summary of Product Characteristics or from:

LEO Pharma, Horizon, Honey Lane, Hurley, Berkshire SL6 6RJ, UK.

e-mail: medical-info.uk@leo-pharma.com LEO Pharma, Cashel Road, Dublin 12, Ireland. e-mail: medical-info.ie@leo-pharma.com

Abbreviated Prescribing Information for Dovobet® (calcipotriol/betamethasone) 50 microgram/g + 0.5 mg/g ointment Please refer to the full Summary of Product Characteristics (SmPC) (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. 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. Avoid inadvertent transfer to scalp, 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. 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 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:** 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:** August 2018.

5/5

Reporting of Suspected Adverse Reactions

Adverse events should be reported.

For the United Kingdom, 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

For the Republic of Ireland, reporting forms and information can be obtained from: HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. Adverse events should also be reported to Drug Safety at LEO Pharma by calling +353 1 4908924 or e-mail: medical-info.ie@leo-pharma.com

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