Pr **Dovobet®**
calcipotriol/
betamethasone dipropionate

Prescribing Summary

Patient Selection Criteria

THERAPEUTIC CLASSIFICATION
Topical Antipsoriatic Agent Vitamin D Analogue/Corticosteroid

INDICATIONS AND CLINICAL USE
Dovobet® ointment is indicated for the topical treatment of psoriasis vulgaris for up to 4 weeks. Dovobet® should not be used on the face.

SPECIAL POPULATIONS

Pregnant Women: The safety of calcipotriol and/or topical corticosteroids for use during pregnancy has not been established. Although studies in experimental animals have not shown teratogenic effects with calcipotriol, studies with corticosteroids have shown teratogenic effects. The use of Dovobet® is not recommended in pregnant women.

Nursing Women: The safety of calcipotriol and/or topical corticosteroids for use in nursing women has not been established. It is not known whether calcipotriol can be excreted in breast milk or if topical application of corticosteroids can lead to sufficient systemic absorption to produce detectable quantities in breast milk. The use of Dovobet® is not recommended in nursing women.

Pediatrics (<18 years of age): There is no clinical trial experience with the use of Dovobet® in children. Children may demonstrate greater susceptibility to systemic steroid-related adverse effects due to a larger skin surface area to body weight ratio as compared to adults.

CONTRAINDICATIONS
Known hypersensitivity to any of the ingredients of Dovobet® ointment. NOT FOR OPHTHALMIC USE. Not for the treatment of viral, fungal or bacterial skin infections, tuberculosis of the skin, syphilitic skin infections, chicken pox, eruptions following vaccinations, and in viral diseases such as herpes simplex, varicella and vaccinia.

Safety Information

WARNINGS AND PRECAUTIONS

General
Due to the content of calcipotriol, hypercalcaemia may occur if the maximum weekly dose (100 g) is exceeded. Serum calcium is quickly normalised when treatment is discontinued. The risk of hypercalcaemia is minimal when the recommendations relevant to calcipotriol are followed (see Monitoring and Laboratory Tests).

The safety of calcipotriol and/or topical corticosteroids for use with children or pregnant or lactating women has not been established. (See SUPPLEMENTAL SAFETY INFORMATION; Special Populations).

Skin
Dovobet® should not be used on the face since this may give rise to itching and erythema of the facial skin. Patients should be instructed to wash their hands after each application of Dovobet® in order to avoid inadvertent transfer to the face. Should facial dermatitis develop in spite of these precautions, Dovobet® therapy should be discontinued.

Prolonged use of corticosteroid-containing preparations may produce striae or atrophy of the skin or subcutaneous tissues. Therefore, it is recommended that corticosteroid treatment be interrupted periodically, and that one area of the body be treated at a time. Topical corticosteroids should be used with caution on lesions of the face, groin and axillae as these areas are more prone to atrophic changes than other areas of the body. If skin atrophy occurs, discontinue treatment. There may be a risk of rebound psoriasis when discontinuing corticosteroids after prolonged periods of use (see ADVERSE REACTIONS).

MONITORING AND LABORATORY TESTS
Treatment with Dovobet® in the recommended amounts (See DOSAGE AND ADMINISTRATION) does not generally result in changes in laboratory values. In patients using greater than the recommended weekly maximum of 100 g of Dovobet®, patients at risk of hypercalcemia, and patients with marginally elevated serum calcium levels, serum calcium should be monitored at suitable intervals.

MOST COMMON ADVERSE REACTIONS
In clinical trials, the most common adverse reaction associated with Dovobet® was pruritus. Pruritus was usually mild and no patients were withdrawn from treatment. Calcipotriol is associated with local reactions such as transient lesional and perilesional irritation.

Rare cases of hypersensitivity reaction have been reported.

To report an adverse reaction please notify Health Canada at 1-866-234-2345 or LEO Pharma Inc. at 1-800-263-4218.

DRUG INTERACTIONS
There is no experience of concomitant therapy with other antipsoriatic drugs.

Administration

Dosing Considerations
Dovobet® is FOR TOPICAL USE ONLY. Not for ophthalmic use. There is no clinical trial experience with the use of Dovobet® in children.

Recommended Dose and Dosage Adjustment
Dovobet® should be applied topically to the affected areas once daily for up to 4 weeks. After satisfactory improvement has occurred, the drug can be discontinued. If recurrence takes place after discontinuation, treatment may be reinstituted.

The maximum recommended adult dose of Dovobet® ointment is 100 g per week.

SUPPLEMENTAL PRODUCT INFORMATION

OTHER POTENTIAL ADVERSE REACTIONS
Prolonged use of corticosteroid-containing preparations may produce striae or atrophy of the skin or subcutaneous tissues. Topical corticosteroids should be used with caution on lesions of the face, groin and axillae as these areas are more prone to atrophic changes than other areas of the body. If skin atrophy occurs, discontinue treatment.

Topical corticosteroids can cause the same spectrum of adverse effects associated with systemic steroid administration, including adrenal suppression. Adverse effects associated with topical corticosteroids are generally local and include: dryness, itching, burning, local irritation, striae, atrophy of the skin or subcutaneous tissues, telangiectasia, hypertrichosis, folliculitis, skin hypopigmentation, allergic contact dermatitis, maceration of the skin, miliaria, or secondary infection. If applied to the face, acne rosacea or perioral dermatitis can occur. In addition, there are reports of the development of pustular psoriasis from chronic plaque psoriasis following reduction or discontinuation of potent topical corticosteroid products.

SUPPLEMENTAL SAFETY INFORMATION

Carcinogenesis
Calcipotriol when used in combination with ultraviolet radiation (UVR) may enhance the known skin carcinogenic effect of UVR. (See TOXICOLOGY, Carcinogenicity, in the Product Monograph).

Endocrine and Metabolism
Application on large areas of damaged skin, under occlusive dressings, or in skin folds should be avoided since it increases systemic absorption of corticosteroids and the risk of adverse effects such as adrenal suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycaemia and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids. Occlusive dressings should not be applied if body temperature is elevated.

All of the adverse effects associated with systemic use of corticosteroids, including adrenal suppression, may also occur following topical administration of corticosteroid-containing products such as Dovobet®, especially in children.

Missed Dose
If a dose is missed, the patient should apply Dovobet® as soon as he/she remembers and then continue on as usual.

Overdosage
Due to the calcipotriol component of DOVOBET (calcipotriol and betamethasone dipropionate), excessive administration (i.e. more than the recommended weekly amount of 100 g) may cause elevated serum calcium, which rapidly subsides when treatment is discontinued. In such cases, it is recommended to monitor serum calcium levels once weekly until they return to normal. Excessive or prolonged use of topical corticosteroids can suppress