

## **PSORIDERM**

### **Cream, Ointment & Scalp Application**

#### **Composition**

##### **Psoriderm cream and Ointment**

Contains Clobetasol propionate 0.5 mg/g

##### **Psoriderm scalp application**

Contains Clobetasol propionate 0.5 mg/g

#### **Action**

##### **Cream, Ointment**

Like other topical corticosteroids, Clobetasol propionate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

##### **Scalp Application**

The corticosteroids are a class of compounds comprising steroid hormones secreted by the adrenal cortex and their synthetic analogs. In pharmacologic doses, corticosteroids are used primarily for their anti-inflammatory and/or immunosuppressive effects. Topical corticosteroids such as Clobetasol propionate are effective in the treatment of corticosteroid-responsive dermatoses primarily because of their anti-inflammatory, antipruritic, and vasoconstrictive actions.

However, while the physiologic, pharmacologic, and clinical effects of the corticosteroids are well known, the exact mechanisms of their actions in each disease are uncertain.

Clobetasol propionate, a corticosteroid, has been shown to have topical (dermatologic) and systemic pharmacologic and metabolic effects characteristic of this class of drugs.

#### **Indications**

##### **Cream and Ointment**

Psoriderm is indicated for short-term treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroid responsive dermatoses. The product is not recommended for use in children under 12 years of age.

##### **Scalp Application**

Psoriderm scalp application is indicated for short-term topical treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses of the scalp. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 ml per week because of the potential for the drug to suppress the HPA axis.

This product is not recommended for use in pediatric patients under 12 years of age.

#### **Contraindications**

##### **Cream and Ointment**

Contraindicated in patients who are hypersensitive to Clobetasol propionate, or to other corticosteroids.

##### **Scalp Application**

Clobetasol propionate scalp application is contraindicated in patients with primary infections of the scalp, or in patients who are hypersensitive to clobetasol propionate, other corticosteroids, or any ingredient in this preparation.

## **Adverse Reactions**

### **Cream and Ointment**

Clobetasol propionate is generally well tolerated when used for 2-week treatment periods. The most frequent adverse events reported for Clobetasol have been local and have included burning sensation, irritation, and itching. Less frequent adverse reactions were stinging, cracking, erythema, and folliculitis, numbness of fingers, skin atrophy and telangiectasia.

The following local adverse reactions are reported infrequently when topical corticosteroids are used as recommended. These reactions are listed in an approximately decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acne-form eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glucosuria in some patients. In rare instances, treatment (or withdrawal of treatment) of psoriasis with corticosteroids is thought to have exacerbated the disease or provoked the postural form of the disease, so careful patient supervision is recommended.

### **Scalp Application**

Clobetasol propionate scalp application is generally well tolerated when used for 2-week treatment periods.

The most frequent adverse events reported for clobetasol propionate scalp application have been local and have included burning and/or stinging sensation and tingling and folliculitis. Less frequent adverse events were itching and tightness of the scalp, dermatitis, tenderness, headache, hair loss, and eye irritation.

The following local adverse reactions are reported infrequently when topical corticosteroids are used as recommended. These reactions are listed in an approximately decreasing order of occurrence: burning, itching, and irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, and allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. In rare instances, treatment (or withdrawal of treatment) of psoriasis with corticosteroids is thought to have exacerbated the disease or provoked the postural form of the disease, so careful patient supervision is recommended.

## **Precautions**

### **General**

#### *Cream and Ointment*

Clobetasol propionate is a highly potent topical corticosteroid that has been shown to suppress the HPA axis at doses as low as 2 grams per day.

Systemic absorption of topical corticosteroids has resulted in reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions that augment systemic absorption include the application of the more potent corticosteroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity.

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. Irritation is possible if Clobetasol propionate contacts the eye. If that should occur, immediate flushing of the eye with a large volume of water is recommended. In the presence of dermatologic infections, the use of an appropriate antifungal or antibacterial agent should be instituted? If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

As with other potent topical corticosteroids, Clobetasol propionate should not be used in the treatment of rosacea and perioral dermatitis. Topical corticosteroids in general should not be used in the treatment of acne or as sole therapy in widespread plaque psoriasis.

#### *Scalp Application*

Clobetasol propionate is a highly potent topical corticosteroid that has been shown to suppress the HPA axis at doses as low as 2 g (of ointment) per day. Systemic absorption of topical corticosteroids has resulted in reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions that augment systemic absorption include the application of the more potent corticosteroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Pediatric patients may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity.

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. Irritation is possible if clobetasol propionate scalp application contacts the eye. If that should occur, immediate flushing of the eye with a large volume of water is recommended.

If the inflammatory lesion becomes infected, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Although clobetasol propionate scalp application is intended for the treatment of inflammatory conditions of the scalp, it should be noted that certain areas of the body, such as the face, groin, and axillae, are more prone to atrophic changes than other areas of the body following treatment with corticosteroids. Frequent observation of the patient is important if these areas are to be treated.

As with other potent topical corticosteroids, clobetasol propionate scalp application should not be used in the treatment of rosacea and perioral dermatitis. Topical corticosteroids in general should not be used in the treatment of acne or as sole therapy in widespread plaque psoriasis.

#### **Information for the Patient**

Patients using topical corticosteroids should receive the following information and instructions:

- This medication is to be used as directed by the physician (and, for scalp application, should not be used longer than the prescribed period.) It is for external use only. Avoid contact with the eyes.
- This medication should not be used for any disorder other than that for which it was prescribed.
- The treated skin area should not be bandaged, otherwise covered, or wrapped so as to be occlusive (unless directed by the physician for cream, ointment).

- Patients should report any signs of local adverse reactions to the physician.
- Patients should inform their physicians that they are using Clobetasol propionate if surgery is contemplated.
- As with other corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, contact the physician.

#### **Laboratory Tests**

The following tests may be helpful in evaluating HPA axis suppression:

- Urinary free cortisol test
- ACTH stimulation test

#### **Pregnancy**

##### *Category C*

Clobetasol propionate has greater teratogenic potential than steroids that are less potent.

There are no adequate and well-controlled studies of the teratogenic effects of topically applied corticosteroids, including Clobetasol, in pregnant women. Therefore, Clobetasol and other topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus, and they should not be used extensively on pregnant patients, in large amounts, or for prolonged periods.

#### **Nursing Mothers**

It is unknown whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing woman.

#### **Paediatric Use**

Use of Clobetasol propionate in children under 12 years of age is not recommended.

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches and bilateral papilledema.

### **Dosage and Administration**

#### **Cream and Ointment**

A thin layer of Psoriderm should be applied with gentle rubbing to the affected skin areas twice daily, once in the morning and once at night. Psoriderm is potent; therefore, treatment must be limited to 2 consecutive weeks, and amounts greater than 50 grams per week should not be used. Psoriderm is not used with occlusive dressings.

#### **Scalp Application**

Psoriderm scalp application should be applied to the affected scalp areas twice daily, once in the morning and once at night.

Psoriderm scalp application is potent; therefore, treatment must be limited to 2 consecutive weeks, and amounts greater than 50 ml per week should not be used.

#### **Over Dosage**

Topically applied Psoriderm can be absorbed in sufficient amounts to produce systemic effects.

**Storage****Cream and Ointment**

Store between 15-30 °C (59-86 °F). Psoriderm cream and ointment should not be refrigerated.

**Scalp Application**

Store between 4-25°C (39-77 °F). Do not use near an open flame.

**Presentation****Psoriderm cream/ ointment**

Tube of 25 grams.

**Psoriderm Scalp Application**

Plastic bottle of 25 ml