# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

PSODERM 0.05% Hair Lotion

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bottle contains:

**Active ingredient:**

Clobetasol 17-propionate.....12.5 mg

**Excipient(s):**

See section 6.1 for excipients.

## 3. PHARMACEUTICAL FORM

Lotion

Colourless, very slightly gel-like liquid

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Indicated for scalp dermatoses responsive to steroids, such as psoriasis and persistent dermatoses.

### 4.2 Posology and method of administration

**Dosage/frequency and duration of administration**

Apply a small amount to the scalp morning and evening until improvement occurs. As with other highly active local steroids, treatment should be discontinued once the disease is under control. PSODERM may be applied for short periods to control flare-ups. If steroid treatment needs to be continued, a less potent preparation should be used.

Children are more sensitive to the local and systemic side effects of corticosteroids; therefore, its use in children over 12 years of age should be limited to 5 days, and application to large areas, in large quantities, and for prolonged periods should be avoided.

**Method of administration**

For external use only.

Applied to the scalp.

After using PSODERM, the bottle cap should be tightly closed. As it contains flammable ingredients, smoking should be avoided during and immediately after use, and it should not be exposed to fire. It should be protected from direct sunlight.

**Additional information on specific populations:**
**Renal/Hepatic impairment**
In cases of systemic absorption (prolonged application over a large area), metabolism and elimination may be delayed, increasing the risk of systemic toxicity. Therefore, it should be used in the lowest possible amount and for the shortest possible time to achieve the desired clinical effect.

**Paediatric population:**
Should not be used for more than 5 days in children over 12 years of age, and the skin should not be covered after application. The lowest effective dose should be used for the shortest possible time in children.

The use of PSODERM is not recommended in the paediatric age group unless absolutely necessary.

**Geriatric population:**
Clinical studies have not identified any difference in response between elderly and younger patients. The higher incidence of hepatic and renal function impairment in the elderly may delay elimination when systemic absorption occurs. Therefore, it should be used in the lowest possible dose and for the shortest possible duration to achieve the desired clinical effect.

## 4.3 Contraindications
It should not be used in cases of scalp infections or hypersensitivity to the preparation.

## 4.4 Special warnings and precautions for use
Local hypersensitivity reactions may present with symptoms similar to those of the diagnosed condition (see Section 4.8 Undesirable effects).

Hypercortisolism (Cushing's syndrome) leading to glucocorticosteroid deficiency and reversible hypothalamic pituitary adrenal (HPA) axis suppression may cause increased systemic absorption of topical steroids in some individuals. When this is observed, either the frequency of application is reduced and the drug is gradually discontinued, or a less potent corticosteroid is applied. Abrupt discontinuation of the medication may lead to glucocorticosteroid deficiency.

Risk factors that increase systemic effects:
- Formulation and effects of topical steroids
- Duration of exposure
- Application to large surface areas
- Occlusiom areas, e.g. creased areas or covered areas
- Increased hydration of the stratum corneum
- Use on thin skin areas, e.g. face

- Use in areas where the skin barrier is compromised, e.g. cracked skin or other causes
- Compared to adults, children may be more susceptible to systemic effects due to greater absorption. This is because children's skin barriers are not fully matured and they have a larger skin surface area relative to their weight compared to adults.

Care should be taken to avoid contact with the eyes. If contact occurs, rinse thoroughly with water.

As repeated applications may cause cataracts and glaucoma, care should be taken to ensure that the product does not enter the eyes.

Smoking should be avoided during application. After application, exposure to fire, flames, or heat, including hair dryers, should be avoided.

Topical steroids should be used with caution in psoriasis; in some cases, rebound relapses, tolerance development, risk of widespread pustular psoriasis, and local and systemic toxicity due to decreased skin barrier function have been reported. Close monitoring of patients is important when topical steroids are used in psoriasis.

Topical corticosteroids are sometimes used to treat dermatitis around chronic leg ulcers. However, this use may be associated with a higher incidence of local hypersensitivity reactions and an increased risk of local infection.

Appropriate antimicrobial therapy should be administered when treating infected inflammatory lesions. Any spread of infection requires discontinuation of corticosteroids and systemic administration of antimicrobial agents.

As the warm and moist environment created by the occlusive dressing may lead to bacterial infection, the skin should be thoroughly cleaned before applying a new dressing.

The corticosteroid with the lowest possible potency that can provide effective treatment should be preferred. The viscosity of the medication is adjusted so that it is not too runny when applied to the scalp and can be easily applied. The design of the bottle and nozzle is intended to allow the medication to be applied directly to the scalp.

It should be used during pregnancy and lactation only under medical supervision.

### 4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use with CYP3A4 inhibitor medications (e.g. ritonavir, itraconazole) has been shown to suppress corticosteroid metabolism, leading to increased systemic exposure. The clinical significance of this interaction depends on the dose and route of administration of the corticosteroid and the potency of the CYP3A4 inhibitor.

**Additional information for specific populations**
No data available.

**Paediatric population:**
No data available.

## 4.6 Fertility, pregnancy and lactation

**General advice**
Pregnancy category: C

**Women of childbearing potential/Contraception**
No special contraception is required for women of childbearing potential. It should not be used extensively, in high doses, or for long periods in women planning pregnancy.

**Pregnancy**
There is insufficient data on the use of clobetasol propionate in pregnant women. Local application of corticosteroids to pregnant animals may cause abnormalities in foetal development. The relevance of this finding to humans has not been established. However, clobetasol should only be used during pregnancy if the expected benefit to the mother outweighs the potential risk to the foetus. It should be used in the lowest possible dose and for the shortest possible duration.

**Lactation**
The safety of topical steroids during lactation has not been established. It is unknown whether topical steroids are systemically absorbed to a level detectable in breast milk.
Clobetasol should only be used during lactation if the expected benefit to the mother outweighs the potential risk to the infant.

If clobetasol is to be used during lactation, it should not be applied to the breast area to prevent accidental ingestion by the infant.

**Reproductive ability/Fertility**
Studies in animals have shown reproductive toxicity. The potential risk to humans is unknown. There are no data evaluating the effect of topical corticosteroids on fertility in humans. Subcutaneous administration of clobetasol to rats did not affect mating performance, but fertility was reduced at high doses.

## 4.7 Effects on the ability to drive and use machines

There are no studies investigating the effect of clobetasol on the use of machinery and vehicles. Based on the adverse reaction profile of topical clobetasol, no adverse effects on these activities are expected.

## 4.8 Undesirable effects

The frequency classification is as follows:
Very common ≥1/10; common ≥1/100, < 1/10; uncommon ≥1/1,000, < 1/100; rare ≥1/10,000, < 1/1,000, very rare < 1/10,000, not known (cannot be estimated from the available data).

**Post-marketing experience**
**Infections and infestations**
Very rare: Opportunistic infections

**Immune system disorders**
Very rare: Local hypersensitivity

**Endocrine disorders**
Very rare: Hypothalamic-pituitary-adrenal (HPA) axis suppression
Cushingoid features (e.g. moon face, central obesity), weight gain/growth retardation in children, osteoporosis, glaucoma, hyperglycaemia/glucosuria, cataracts, hypertension, weight gain/obesity, decreased endogenous cortisol levels, alopecia, trichorhexis

**Skin and subcutaneous tissue disorders**
Common: Itching, localised burning and pain in the skin
Uncommon: Skin atrophy*, skin striations*, telangiectasia*
Very rare: Skin thinning*, wrinkling*, skin dryness*, pigmentation changes*, hypertrichosis, exacerbation of underlying symptoms, allergic contact dermatitis, pustular psoriasis, erythema, rash, urticaria, acne
* Associated with local and systemic effects of hypothalamic-pituitary-adrenal (HPA) axis suppression.

**General disorders and administration site conditions**
Very rare: Irritation/pain at the application site

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

## 4.9 Overdose and treatment

Topically applied clobetasol may be absorbed to a degree that produces systemic effects. Acute overdose is not expected; however, chronic overdose or misuse may result in symptoms of hypercortisolism. In case of overdose, clobetasol should be discontinued by reducing the

frequency of application or switching to a less potent corticosteroid due to the risk of glucocorticosteroid insufficiency.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Very potent corticosteroids (topical dermatological) (group IV)
ATC code: D07AD01

Topical corticosteroids reduce late-phase allergic reactions by decreasing mast cell density, reducing chemotaxis and eosinophil activation, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and suppressing arachidonic acid metabolism.

Topical corticosteroids possess anti-inflammatory, antipruritic, and vasoconstrictive properties.

### 5.2 Pharmacokinetic properties

**General properties**

Absorption:
Topical steroids can be systemically absorbed through intact skin. The amount of topical corticosteroids absorbed through the skin depends on many factors, such as the vehicle used and the integrity of the epidermal barrier. Occlusive application, inflammation, and/or other skin diseases can also increase the degree of absorption.

Distribution:
After absorption through the skin, they exhibit distribution similar to systemically administered corticosteroids. Since circulating levels are below the detection limit, special pharmacodynamic measurements are required to assess the systemic
exposure.

Biotransformation:
Topical corticosteroids use the same metabolic pathways as systemically administered corticosteroids after absorption through the skin. They are primarily metabolised by the liver.

Elimination:
They are excreted via the kidneys. Additionally, some metabolites are excreted via bile.

### 5.3 Preclinical safety data

Long-term animal studies have not been conducted to investigate the carcinogenic potential of clobetasol propionate.

Clobetasol propionate was not mutagenic in a series of in vitro bacterial cell assays. In fertility studies, subcutaneous administration of clobetasol propionate at doses of 6.25–50 micrograms/kg/day did not affect mating in rats; fertility was reduced only at a dose of 50 micrograms/kg/day.

Subcutaneous administration of clobetasol propionate during pregnancy in mice (≥100 micrograms/kg/day) and rats (400 micrograms/kg/day) ≥0.1 mg/kg/day or in rabbits (1–10 micrograms/kg/day) caused foetal abnormalities, including cleft palate.
In the rat study, some animals were allowed to breed, and developmental retardation was observed in the F1 generation at a dose of ≥100 micrograms/kg/day. No treatment-related effects were observed on F1 reproductive performance or in the F2 generation.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carbopol 940
Isopropyl Alcohol
Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Store at room temperature below 25°C.

After using PSODERM, the bottle cap must be tightly closed. As it contains flammable content, smoking should be avoided during and immediately after use, and it should not be exposed to fire. It should be protected from direct sunlight.

### 6.5 Nature and contents of container

Box containing a polyethylene bottle with a dropper cap, 25 ml

### 6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

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## 8. MARKETING AUTHORIZATION NUMBER(S)

235/65

## 9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization : 10.10.2011
Date of last renewal :

## 10. DATE OF REVISION OF THE TEXT