PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

CLOBETASOL CREAM SHALINA

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clobetasol propionate USP 0,05 % w/w

Each gram of CLOBETASOL CREAM SHALINA contains 0,5 mg (0,05 % w/w) of clobetasol propionate.

Preservatives:

Methyl Hydroxybenzoate BP 0,15 % w/w

Propyl Hydroxybenzoate BP 0,05 % w/w

Chlorocresol BP 0,04 % w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White, semi-solid cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Short term use in the treatment of steroid responsive dermatoses resistant to other less potent topical corticosteroids such as: seborrhoeic dermatitis, atopic dermatitis, lichen simplex chronicus, pruritis ani, psoriasis, later phase of allergic contact dermatitis, later phase of irritant dermatitis, discoid lupus erythematosus and lichen planus.

4.2 Posology and method of administration

Posology

Apply once or twice daily sparingly to the affected area until improvement occurs. Therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days. If a longer course is necessary, it is recommended that treatment should not be continued for longer than four weeks without the patient's condition being reviewed.

Repeated short courses of CLOBETASOL CREAM SHALINA may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.

In very resistant lesions, especially where there is hyperkeratosis, the treatment area must be occluded for part of each 24 hours.

Thereafter improvement can usually be maintained by application without occlusion.

Paediatric population

No data are available.

Method of administration

For topical use only.

4.3 Contraindications

- Patients with hypersensitivity to clobetasol propionate or to any of the excipients listed in section 6.1.
- CLOBETASOL CREAM SHALINA should not be used in the presence of bacterial (including tuberculous), fungal or viral infections of the skin.
- Avoid use in ulcerative skin lesions and in rosacea.
- Application to ulcers of the leg.
- Long-term use is contraindicated in patients with diabetes mellitus or tuberculosis.
- The following conditions should not be treated with CLOBETASOL CREAM SHALINA:
  - Untreated cutaneous infections
  - Acne vulgaris
  - Pruritus without inflammation
  - Perianal and genital pruritus
  - Perioral dermatitis.

- The more potent corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, CLOBETASOL CREAM SHALINA should not be used during pregnancy (see section 4.6).
- Clobetasol propionate is contraindicated in dermatoses in children under one year of age, including dermatitis and nappy eruptions.

4.4 Special warnings and precautions for use

FOR EXTERNAL USE ONLY.

Cases of osteonecrosis serious infections (including necrotizing fasciitis) and systemic immunosuppression (sometimes resulting in reversible Kaposi's sarcoma lesions) have been reported with long-term use of clobetasol propionate beyond the recommended doses. In some cases, patients used concomitantly other potent oral/topical corticosteroids or immunosuppressors (e.g. methotrexate, mycophenolate mofetil). If treatment with local corticosteroids is clinically justified beyond 4 weeks, a less potent corticosteroid preparation should be considered.

Clobetasol propionate should be used with caution in patients with a history of local hypersensitivity to other corticosteroids or to any of the excipients in the preparation. Local hypersensitivity reactions (see section 4.8) may resemble symptoms of the condition under treatment.

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the medicine gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (see section 4.8).

CLOBETASOL CREAM SHALINA may under certain circumstances, be absorbed through the skin in sufficient amounts to produce systemic effects, since the pharmacokinetic pathway is similar to systemically administered corticosteroids. As CLOBETASOL CREAM SHALINA contains a highly potent corticosteroid, the risk associated with systemic absorption is enhanced.

Risk factors for increased systemic effects are:

- Potency and formulation of topical steroid.
- Duration of exposure.
- Application to a large surface area.
- Absorption (and a risk of subsequent toxicity) is also enhanced by application for prolonged periods under occlusive dressings, by application to extensive areas or when the skin is broken.
- Increased hydration of the stratum corneum.
- Use on thin skin areas such as the face.
- Use on broken skin or other conditions where the skin barrier may be impaired.
- Children may absorb proportionally larger amounts of CLOBETASOL CREAM SHALINA because of a larger skin surface area to body-mass ratio, and thus be more susceptible to systemic toxicity. Tight fitting nappies or plastic pants should not be used on an infant being treated in the nappy area, as these garments may constitute occlusive dressings.

Areas of the body most likely to suffer local damage are the face and eyelids; the intertriginous areas, the cheek, axillae, etc. are more permeable.

Infection risk with occlusion:

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Use in Psoriasis:

Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

Concomitant infection:

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Chronic leg ulcers:

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

Application to the face:

Application to the face is undesirable as this area is more susceptible to atrophic changes.
If used on the face, treatment should be limited to 5 days.

Application to the eyelids:

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataract and glaucoma might result from repeated exposure. If clobetasol propionate does enter the eye, the affected eye should be bathed in copious amounts of water.

Visual disturbance:

Visual disturbance has been 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 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.

CLOBETASOL CREAM SHALINA contains paraffin. Instruct patients not to smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product, burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Use with care in porphyria.

Paediatric population

Special care should be exercised in infants and children. Long-term topical use is best avoided, especially in children under 12 years of age.

Children are more susceptible to develop atrophic changes with the use of topical corticosteroids.

Duration of treatment for children and infants:

Courses should be limited, if possible, to five days and reviewed weekly. Occlusion should not be used.

Excipients

CLOBETASOL CREAM SHALINA contains chlorocresol which may cause local skin reactions and/or allergic reactions. Treatment with CLOBETASOL CREAM SHALINA should be discontinued if this occurs.

4.5 Interaction with other medicines and other forms of interaction

Co-administered medicines that can inhibit CYP3A4 (e.g. ritonavir and itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

4.6 Fertility, pregnancy and lactation

Pregnancy

The more potent corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded.

The safety of CLOBETASOL CREAM SHALINA in pregnancy has not been established (see section 4.3).

Breastfeeding

The safety of CLOBETASOL CREAM SHALINA during lactation has not been established.

If used during lactation clobetasol propionate as in CLOBETASOL CREAM SHALINA should not be applied to the breasts to avoid accidental ingestion by the infant.

Fertility

There are no data available.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of clobetasol propionate on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical clobetasol propionate.

4.8 Undesirable effects

b) Tabulated list of adverse reactions

Side effects are grouped in order of frequent, less frequent and frequency unknown.

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (Cannot be estimated from the available data)
Infections and infestations		Opportunistic infection	Worsening or spreading of local infections
Immune system disorders		Hypersensitivity, generalised rash	
Endocrine disorders		Hypothalamic-pituitary adrenal (HPA) axis suppression: Cushingoid features: (e.g. moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, hyperglycaemia/ glucosuria, hypertension, obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis	
Eye disorders		Cataract, central serous chorioretinopathy, glaucoma	Blurred vision

Skin and subcutaneous tissue disorders	Pruritus, local skin burning /skin pain	Skin atrophy*, striae*, telangiectasias*, loss of skin collagen*, skin dryness*, local hypopigmentation of deeply pigmented skins*, hypertrichosis, exacerbation of underlying symptoms, allergic contact dermatitis/dermatitis, pustular psoriasis, erythema, rash, urticaria, acne	Withdrawal reactions – redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4), increased fragility of cutaneous vessels may result in bruising and purpura, rosacea-like dermatitis, perioral dermatitis, maceration of the skin and miliaria
General disorders and administrative site conditions		Application site irritation	

*Skin features secondary to local and/or systemic effects of hypothalamic-pituitary adrenal (HPA) axis suppression.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine CLOBETASOL CREAM SHALINA is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za.

4.9 Overdose

Symptoms

Topically applied clobetasol may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur (see section 4.8).

Management

In the event of overdose, clobetasol propionate should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 13.4.1 Dermatological preparation - Corticosteroids without anti-infective agents

Pharmacotherapeutic group: Corticosteroids, very potent (group IV)

ATC code: D07AD01

Mechanism of action

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Pharmacodynamic effects

Clobetasol propionate is a highly potent topical corticosteroid, have anti-inflammatory, antipruritic, and vasoconstrictive properties.

5.2 Pharmacokinetic properties

Absorption: Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Mean peak plasma clobetasol propionate concentrations of 0,63 ng/ml occurred in one study eight hours after the second application (13 hours after an initial application) of 30 g clobetasol propionate 0,05 % ointment to normal individuals with healthy skin. Following the application of a second dose of 30 g clobetasol propionate cream 0,05 % mean peak plasma concentrations were slightly higher than the ointment and occurred 10 hours after application.

In a separate study, mean peak plasma concentrations of approximately 2,3 ng/ml and 4,6 ng/ml occurred respectively in patients with psoriasis and eczema three hours after a single application of 25 g clobetasol propionate 0,05 % ointment.

Distribution: The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.

Biotransformation: Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination: Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Cetomacrogol 1000
- Cetostearyl alcohol
- Chlorocresol BP 0,04 % w/w
- Methyl hydroxybenzoate 0,15 % w/w
- Propyl hydroxybenzoate 0,05 % w/w
- Propylene glycol
- Sodium dihydrogen phosphate
- White soft paraffin
- Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 30 °C.

Keep the tube in the outer carton until required for use.

This medicine does not require any special storage conditions.

6.5 Nature and contents of container

White semi-solid cream is packed in a white multi-layered based aluminium lami-tube with a cap. The tube is placed in a carton together with a leaflet.

Pack sizes: 15 g and 30 g.

Not all pack sizes may be marketed.

Tube is enclosed in an outer carton until required for use.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

Pharmadyne Healthcare (Pty) Ltd

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1619

8 REGISTRATION NUMBER

57/13.4.1/0040

9 DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

25 March 2025

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