

pharmaniaga[®]



Dermapro

Cream / Ointment

Clobetasol propionate 0.05%

DESCRIPTION

Pharmaniaga Dermapro cream

White, smooth textured cream.

Pharmaniaga Dermapro ointment

A smooth white ointment.

COMPOSITION

Each gram of cream or ointment contains Clobetasol propionate 0.05% w/w.

PHARMACODYNAMICS

Clobetasol propionate is a high potency glucocorticoid and has local anti-inflammatory action.

PHARMACOKINETICS

Clobetasol propionate can undergo systemic absorption across the stratum corneum. Once absorbed it enters pharmacokinetics pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolized primarily in the liver and excreted by the kidneys.

Repeated application results in a cumulative depot effect in the skin, which may lead to a prolonged duration of action, increased side-effects and increased systemic absorption.

INDICATIONS

Clobetasol is indicated for short-term treatment of inflammation and/ or pruritus associated with acute and chronic corticosteroid-responsive skin disorders.

CONTRAINDICATIONS

Intolerance to corticosteroids.

ADVERSE REACTIONS

Application of corticosteroids to the skin has led to loss of skin collagen and subcutaneous atrophy, local hypopigmentation of deeply pigmented skins, burning and stinging sensation, itching, dilatation of superficial blood vessels in prolonged and intensive treatment, provoke pustular form of disease in the treatment of psoriasis.

PRECAUTIONS

When applied topically, particularly to large areas, or when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic effects, resulting in reversible HPA axis suppression. Therefore, patients should be evaluated periodically using the urinary free cortisol and ACTH stimulation tests.

Paediatrics

Children and adolescents may demonstrate greater susceptibility to adrenal suppression, Cushing's syndrome, intracranial hypertension, and growth retardation. This is due to larger skin surface area to body-weight ratio which results in greater amount of systemic absorption.

PREGNANCY AND LACTATION

Pregnancy

The more potent corticosteroids have shown to be teratogenic in animals after dermal application. Clobetasol propionate has not been tested for teratogenicity by this route; however, it is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rabbit and the mouse. 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 should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Appropriate antifungal or antibacterial should be instituted in the presence of dermatologic infections. Clobetasol products are not to be used in the eye, to be avoided on the face, groin or axillae, not to be

210mm

148.5mm

210mm

used for treating acne, rosacea or perioral dermatitis. If local irritation occur, discontinue the therapy.

Lactation

Safety of use during lactation has not been established. However, systemic corticosteroids are excreted in breast milk and may cause unwanted effects in the infant such as growth suppression.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

There have been no studies to investigate the effect of clobetasol 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.

DRUG INTERACTIONS

Co-administered drugs that can inhibit CYP3A4 (eg 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.

DOSAGE AND ADMINISTRATION

Usual adult dosage:

Apply a thin film to the affected area two or three times a day up to a maximum of 50 g per week. The duration of therapy should be limited to brief periods.

Usual paediatric dosage:

Use is not recommended in children up to 12 years of age.

Treatment should be limited to two consecutive weeks and total dose should not exceed 50 g per week.

OVERDOSAGE

Topically applied cream or ointment can be absorbed in sufficient amounts to produce systemic effects. Since there is no specific antidote available, treatment is symptomatic, supportive and consists of discontinuance of topical corticosteroid therapy. Gradual withdrawal of the preparation may be necessary.

ROUTE OF ADMINISTRATION

Topical.

STORAGE CONDITIONS

Store below 30°C.

Keep container tightly closed.

Protect from light.

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

PRESENTATION

Tubes of 15 g.

Date of revision : 26 Aug 2026

PRODUCT REGISTRATION HOLDER:

Pharmaniaga Manufacturing Berhad (198001006232)
No. 11A, Jalan P/1, Kawasan Perusahaan Bangi,
43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

MANUFACTURER

InspiraPharma Sdn. Bhd. (200401023395)
Lot 24 & 25, Jalan 8,
Kawasan Perusahaan Bakar Arang,
08000 Sungai Petani,
Kedah Darul Aman, Malaysia.

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