# CREDAVATE

**Instructions for the medicinal product**

**Trade name:** Credavate.
**International nonproprietary name:** Clobetasol.
**Dosage form:** Ointment for external use.
**Composition:**
Clobetasol Propionate BP 0.05% w/w.
**Pharmacotherapeutic group:** Glucocorticosteroids (GCS) for external use.
**ATC Code:** D07AD01.
**Pharmacologic property:**
*Pharmacodynamics:*
Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.
*Pharmacokinetics:*
Percutaneous penetration of clobetasol propionate varies among individuals and can be increased by the use of occlusive dressings, or when the skin is inflamed or diseased.
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.
Following percutaneous absorption of clobetasol propionate, the drug probably follows the metabolic pathway of systemically administered corticosteroids, i.e. metabolised primarily by the liver and then excreted by the kidneys. However, systemic metabolism of clobetasol has never been fully characterised or quantified.
**Indications for use:**
- Psoriasis (excluding widespread plaque psoriasis);
- Eczema (in refractory form);
- Lichen ruber planus;
- Discoid lupus erythematosus;
- Other skin diseases that are resistant to less active glucocorticoid therapy;
- Skin disease resistant to less active GCS treatment, for topical use.

*Credavate ointment* recommended for skin lesions, accompanied by dryness, hyperkeratosis, thickening as ointment based drug helps to preserve moisture in the skin.
**Contraindications:**
- Hypersensitivity to components of the drug;
- Rosacea;
- Acne vulgaris;
- Skin cancer;
- Hyde`s disease;
- Perioral dermatitis;
- Perianal and genital itching;
- Bacterial, viral and fungal infections of the skin (herpes simplex, varicella, tuberculosis cutis, actinomycosis);
- Widespread plaque and pustular psoriasis;
- Children up to 1 year;
- Lactation.

*Pregnancy and lactation:*
GCS for topical use should not be used cautiously during pregnancy not for a long time at high doses, and only if clearly needed. Discuss the benefits and risks with your doctor. Small amounts of this medication may appear in breast milk. Consult with your doctor before breast-feeding.
**Dosage and Direction for use:**
For topical use only.
Apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations, therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days. If no improvement is seen within two to four weeks, reassessment of the diagnosis, or referral, may be necessary.
Repeated short courses of Credavate 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 anti-inflammatory effect of Credavate can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.
**Side effects:**
*Endocrine disorders:* Features of Cushing's syndrome. As with other topical corticosteroids, prolonged use of large amounts, or treatment of extensive areas can result in sufficient systemic absorption to produce the features of Cushing's syndrome. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the nappy may act as an occlusive dressing.
Provided the weekly dosage is less than 50g in adults, any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage.
*Skin and subcutaneous tissue disorders:* Local skin burning, local atrophy, striae, thinning, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms, pustular psoriasis.
Prolonged and intensive treatment with highly-active corticosteroid preparations may cause local atrophic changes, such as thinning and striae.
Treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

**Overdose:**
Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse, the features of hypercortisolism may appear and in this situation topical steroids should be reduced or discontinued gradually, under medical supervision.
**Drug interactions:**
No data.
**Cautions:**
Long term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur readily even without occlusion. If Credavate is required for use in children, it is recommended that the treatment should be reviewed weekly. It should be noted that the infant's napkin may act as an occlusive dressing.
If used in childhood or on the face, courses should be limited if possible to five days and occlusion should not be used.
The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.
If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.
If Credavate Ointment does enter the eye, the affected eye should be bathed in copious amounts of water.
Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.
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 systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.
*Effects on ability to drive vehicles and management mechanisms:*
Credavate ointment is not expected to have any effects.
**Presentation:**
30 g aluminium tube with instruction for use in a carton box.
**Storage:**
Keep in dry place protected from light at temperature below 30°C. Keep out of reach of children.
**Expiry date:**
Labeled. Do not use after expiry date.
**Distribution conditions:**
Non-prescribed medicine.