AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
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1.5.3 Patient Information Leaflet (PIL)

AGOBATE CREAM

(Clobetasol Propionate Cream BP 0.05% w/w)

Composition:
Each gram contains:
Clobetasol Propionate BP ..... 0.5 mg
Cream base ..... Q.S.

Therapeutic indications:
Clobetasol is a very potent topical corticosteroid indicated for adults, elderly and children over 1 year for the short term treatment only of more resistant inflammatory and pruritic manifestations of steroid responsive dermatoses unresponsive to less potent corticosteroids.
These include the following:

- Psoriasis (excluding widespread plaque psoriasis)
- Recalcitrant dermatoses
- Lichen planus
- Discoid lupus erythematosus
- Other skin conditions which do not respond satisfactorily to less potent steroids.

Posology
Clobetasol propionate belongs to the most potent class of topical corticosteroids (class I) and prolonged use may result in serious undesirable effects. If treatment with a local corticosteroids is clinically justified beyond 4 weeks, a less potent corticosteroids preparation should be considered. Repeated but short courses of clobetasol propionate may be used to control exacerbations.

Method of administration
For topical administration.

Contraindications:
Hypersensitivity to the active substance or to any of the excipients listed below
The following conditions should not be treated with Agobate:

- Untreated cutaneous infections
- Rosavea
- Acne vulgaris
- Pruritus without inflammation
- Perianal and genital pruritus
- Perioral dermatitis.

Clobetasol is contraindicated in dermatoses in children under on year of age, including dermatitis and nappy eruptions.

Special warnings and precautions for use:
Clobetasol 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 may resemble symptoms of the condition under treatment.
Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroids 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 drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroids. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency.

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.

Application to the face
Application to the face is undersirable 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 Agobate does enter the eye, the affected eye should be bathed in copious amounts of water.

Interaction with other medicinal product and other forms of interaction:
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 depend on the dose route of administeration of the corticosteroids and the potency of the CYP3A4 inhibitor.

Fertility, pregnancy and lactation:

Pregnancy
There are limited data from the use of clobetasol in pregnant women. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to humans has not been established. Administration of clobetasol during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.

Breast-feeding
The safe use of topical corticosteroids during lactation has not been established. It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of clobetasol propionate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant. If used during lactation clobetasol propionate should not be applied to the breasts to avoid accidental ingestion by the infant.

Fertility
There are no data in humans to evaluate the effect of topical corticosteroids on fertility. Clobetasol administered subcutaneously to rats had no effect upon mating performance; however, fertility was decreased at the highest dose.

Effect on ability to drive and use machines:
There have been no studies to investigate the effect of clobetasol on driving performance or the ability to operate machinery. A dertimental effect on such activities would not be anticipated from the adverse reaction profile of topical clobetasol.

Storage:
Store under normal storage conditions (15°C to 30°C).
Protect from light.
Keep out of reach of children.

Presentation:
10/15/20/30 gm tube in a carton.

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Manufactured in India by:
AGOG PHARMA LTD.
Plot No. 33, Sector II, The Vasai Taluka Indl. Co-op. Estate Ltd., Vasai (East), Dist. Thane. INDIA.