

Clobesol

Clobetasol Propionate USP 0.05%

Cream and Ointment

Composition :

Clobesol Cream: Each gram Cream contains Clobetasol Propionate USP 0.5 mg.

Clobesol Ointment: Each gram Ointment contains Clobetasol Propionate USP 0.5 mg.

Pharmacology :

Clobesol has both local anti-inflammatory and immunosuppressive activity. Thus **Clobesol** inhibits the adherence of neutrophils and monocyte-macrophages to the capillary endothelial cells of the inflamed area. The drug blocks the effect of macrophage migration inhibitory factor and decreases the activation of plasminogen to plasmin. Clobesol reduces the number of human leukocytes antigen & also inhibits phospholipase A₂ activity via formation of lipocortin. Thus Clobesol reduces the formation of prostaglandins and leukotriens in the local tissues.

Indications :

- Initial control of all forms of hyper acute eczema in all age groups
- Chronic hyperkeratotic eczema of the hands and feet and patches of chronic lichen - simplex
- Chronic hyperkeratotic psoriasis of any area of the body
- Severe acute photosensitivity
- Acute contact dermatitis
- Hypertrophic lichen planus
- Lupus erythematosus
- Localized bullous disorders
- Keloid scarring
- Pretibial myxoedema, vitiligo, suppression of reactions after cryotherapy

Dosage and Application :

Clobesol should be applied with gentle rubbing to the affected skin areas twice daily. Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similarly to systemically administered corticosteroids. For acute dermatitis — twice daily application may be appropriate for short periods of Time e.g. 1-2 weeks, although evidence now suggests that once daily application is sufficient. Long-term treatment should probably be limited to intermittent therapy as skin atrophy has been shown to persist for 3 days after single application. Dosage should not normally exceed 50 g per week and the duration of a course should not be more than 4 weeks. The potency can be further enhanced by the use of occlusive dressing.

Side Effects :

The use of large amount of Clobetasol Propionate for a long period of time over very large areas of the body can lead to produce adrenal suppression, cushing syndrome; hypercorticism; pigmentation; atrophic changes such as thinning, striae etc.

Contraindications :

- Cutaneous infections such as impetigo, tinea corporis, and herpes simplex.
- Infestation such as scabies.
- Acne vulgaris.
- Children under one year
- Hypersensitivity
- Rosacea, gravitational ulceration & perioral dermatitis.

Precautions :

Avoid long- term therapy particularly in children, in whom adrenal suppression occurs readily. If **Clobesol** is required for use in children it is recommended that the treatment should be weekly reviewed. Avoid prolonged application to face, because the face than other area of the body exhibits more atrophic changes with potent corticosteroids. Discontinue the use if there is spread of infection. Avoid contact with eyes.

Use in Pregnancy :

Clobesol should be avoided in pregnant women.

Use in Lactation :

Mothers using large amount of the drug should be aware of potential excretion in milk.

Pediatric Use :

The drug may be used in pediatric patients in appropriate dosage, but large quantities for prolonged period should be avoided. It is contraindicated in children less than one year.

Drug Interactions :

No hazardous interactions have been found.

Information for Patients :

1. This medication is to be used as directed by the physician and should not be used longer than the prescribed time period. It is for external use only. Avoid contact with eyes.
2. The treated skin area should not be bandaged or otherwise covered but wrapped so as to be occlusive.
3. This medication should not be used for any disorder other than that for which it was prescribed.
4. Patients should report any sign of local adverse reactions to the physicians.

Storage :

- Store in a cool and dry place, protect from light.
- Keep out of the reach of children.
- Close the mouth of tube well after each application.
- Do not freeze.

Packing :

Clobesol Cream : Each tube contains 10 g of cream.

Clobesol Ointment : Each tube contains 10 g/30 g of ointment.

20002104/03