



Winclas™ Cream

Clascoterone INN 1%

Composition

Winclas™ Cream: Each gram cream contains Clascoterone INN 10 mg.

Pharmacology

Topical Clascoterone (Cortisolone 17 α -propionate) is a novel antagonist of androgen receptors in the skin. Within the skin, it binds to androgen receptors with high affinity. By competing with androgens for binding to androgen receptors, Clascoterone works by blocking the androgen receptor signalling cascades that promotes acne pathogenesis such as sebaceous gland proliferation, excess sebum production and inflammatory pathways.

Indication and Uses

Clascoterone cream is indicated for the topical treatment of acne vulgaris in patients of 12 years of age and older.

Dosage & Administration

Clean the affected area gently then apply a thin uniform layer of Clascoterone cream twice per day in the morning and evening to the affected area. Avoid accidental transfer of Clascoterone cream into eyes, mouth or other mucous membranes. If contact with mucous membranes occurs, this should be rinsed thoroughly with water. Or, as directed by the physician.

Contraindication

Data of contraindication of Clascoterone cream is not available.

Warning and Precaution

Local irritation: Pruritus, burning, skin redness or peeling may be experienced with Clascoterone cream. If these effects occur, discontinue or reduce the frequency of application of Clascoterone cream.

- Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with Clascoterone
- Paediatric patients may be more susceptible to systemic toxicity
- Elevated potassium levels (hyperkalemia) are observed in some subjects during the clinical trials

Side Effects

Most common adverse reactions occurring in between 7% to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally more than 3% of patients may suffer from edema, stinging and burning.

Use in Pregnancy and Lactation

There is no available data on the use of Clascoterone cream in pregnant women to evaluate a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

There is no data regarding the presence of Clascoterone or its metabolite in human milk or the effects on milk production and breastfed infant.

Use in Children and Adolescents

Safety and effectiveness of Clascoterone cream for the topical treatment of acne vulgaris have not been established in pediatric patients under 12 years of age.

Drug Interactions

No clinical study evaluating the drug interaction of Clascoterone cream has been conducted.

Overdosage

There is no experience of overdosage with Clascoterone.

Storage

Prior to dispensing, store at 2 °C to 8 °C in a refrigerator; do not freeze. Once dispensed to patient, store at room temperature (20 °C to 25 °C). Discard unused portion 180 days after date of dispensing or 1 month after first opening, whichever is sooner. Keep away from light and out of the reach of children.

Commercial Pack

Winclas™ Cream: Each tube contains 10 gm cream.



Manufactured by

Incepta Pharmaceuticals Ltd

Dhamrai Unit, Dhaka, Bangladesh

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