



# Clascoterone Cream Therapeutic Cheat Sheet

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#### TRADE NAME

> WINLEVI®

#### **MECHANISM OF ACTION**

> Clascoterone 1% cream or cortexolone 17a-propionate is an androgen inhibitor that works by competing with dihydrotestosterone (DHT) for binding to androgen receptors in sebocytes.1-3 Decreased gene transcription results in reduced sebum production as well as proinflammatory cytokine production.2 Androgen receptors are targeted at the site of application therefore systemic activity is limited.<sup>23</sup>

#### FDA-APPROVED USE

> Acne vulgaris in patients 12 years of age and older

### **OFF-LABEL USES**

> Androgenic alopecia 4,5

# DOSING

- > Topical application on clean, dry skin to affected areas twice a day.1
- > There is no standardized treatment duration, but clinical trials utilized twice a day dosing for 12 weeks duration.

# SIDE EFFECTS ASSOCIATED

- > Erythema (7-12%)
- > Pruritus (7-12%)
- > Scaling/dryness (7-12%)
- > Edema (>3%)
- > Stinging (>3%)
- > Burning (>3%)

#### **WARNINGS**

- > Local skin irritation can occur especially when used with other irritating topical medications. If this occurs, discontinue or reduce the frequency of clascoterone application.
- Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment. It is recommended not use the product over large surface areas or under occlusive dressings. Pediatric patients may be more susceptible to HPA axis suppression. If HPA axis suppression occurs, one should withdraw the drug.

# **CONTRAINDICATIONS**

> None

# **PREGNANCY**

- There are no studies or adequate data on risk associated in pregnant women. In animal reproduction studies, there were no clascoterone-related maternal toxicity at doses up to 25 mg/kg/day.¹ However, there were malformations noted in fetuses at all doses including omphalocele, visceral and external malformations.¹
- There is no data on the presence of clascoterone in human milk, effects on milk production, or effects on infants who are breastfed.

#### **MONITORING**

> No recommended monitoring guidelines