

Duac 3% and 5% UK Prescribing Information

(Please refer to full Summary of Product Characteristics before prescribing)

Duac® Once Daily 10mg/g + 30mg/g Gel (clindamycin phosphate 1%, benzoyl peroxide 3%) and **Duac® Once Daily 10mg/g + 50mg/g Gel** (clindamycin phosphate 1%, benzoyl peroxide 5%).

Indication: Topical treatment of mild to moderate acne vulgaris, particularly inflammatory lesions.

Dosage and administration: *Adults and adolescents (aged ≥12 years):* Apply thin layer once daily (evening) to affected area after washing. Wash hands after use. Do not exceed more than 12 weeks of continuous use.

Contra-indications: Hypersensitivity to clindamycin, lincomycin, benzoyl peroxide or any of the excipients.

Precautions: Avoid contact with mouth, eyes, lips, mucous membranes and irritated/broken skin. Caution advised in application to sensitive areas; patients with history of regional enteritis, ulcerative colitis or antibiotic-associated colitis; atopic patients in whom further skin drying may occur; and concomitant topical acne therapy. Increased peeling and reddening may occur during the first weeks of treatment. Depending upon the severity, reduce application frequency or temporarily discontinue use. Discontinue if severe local irritancy, prolonged or significant diarrhoea, or abdominal cramps. Sunlamps should not be used and deliberate or prolonged exposure to sun should be avoided or minimised. Sunburn should be resolved before use. *Clindamycin resistance:* Patients with a recent history of systemic or topical clindamycin or erythromycin use are more likely to have pre-existing anti-microbial resistant *Propionibacterium acnes* and commensal flora. *Cross*

resistance: May occur with other antibiotics when using antibiotic monotherapy. Avoid contact with hair, fabrics furniture or carpeting due to bleaching.

Interactions: Use with caution with concomitant topical antibiotics, medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol and/or astringents, as a cumulative irritant effect may occur. Caution with concomitant use of neuromuscular blocking agents. Avoid concomitant use with tretinoin, isotretinoin and tazarotene. Do not use in combination with erythromycin-containing products. Concomitant use with topical sulfonamide-containing products may cause skin and facial hair to temporarily change colour (yellow/orange). **Fertility, pregnancy and lactation:** Safety in human pregnancy and breastfeeding has not been established and should only be prescribed after a careful risk/benefit assessment. Do not apply to breast area if used during lactation. No data on the effect on fertility in humans.

Side effects: Erythema, peeling, dryness, pruritus, dermatitis, burning sensation, photosensitivity, headache, application site pain, allergic reactions including anaphylaxis. Consult the SPC in relation to other adverse reactions. **Legal category:** POM. **NHS list price:** Duac 10mg/g + 30mg/g Tube: 30g - £13.14, 60g - £26.28; Duac 10mg/g + 50mg/g Tube: 30g - £13.14, 60g - £26.28. **Market authorisation (MA) number:** Duac 10mg/g + 30mg/g - PL 19494/0251; Duac 10mg/g + 50mg/g - PL 19494/0075. **MA holder:** GlaxoSmithKline UK Limited, Trading as Stiefel, Stockley Park West, Uxbridge, Middlesex, UB11 1BT. **Last date of revision:** July 2015. UK/CBP/0027/13(4)

Duac® is a registered trade mark of Stiefel, a GSK company.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Stiefel, a GSK company on 0800 221 441.

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